



February 2017

MEDICAL DEVICES

Cancer Risk Led FDA to Warn Against Certain Uses of Power Morcellators and Recommend New Labeling

Why GAO Did This Study

In December 2013, media reports raised concerns regarding the use of power morcellators in the surgical treatment of women with uterine fibroids. These concerns focused on the spread of an unsuspected uterine cancer after such use of the devices.

GAO was asked to review power morcellator medical devices. This report examines (1) the number of 510(k) submissions for power morcellators FDA cleared, and the extent to which the agency determined the devices had new intended uses or new technological characteristics; (2) FDA's understanding of any concerns with the use of power morcellators to treat uterine fibroids prior to receiving adverse event reports, and the actions FDA has taken in response to these reports; and (3) the professional standards and guidance for physicians regarding the use of power morcellators, and the information device manufacturers provided. GAO reviewed documentation of FDA's decision-making and guidance and manufacturers' device labeling, and interviewed FDA officials. In addition, GAO reviewed documents and contacted officials from 10 professional societies and other organizations that have a potential interest in the use of power morcellators, and three health care providers that performed gynecological procedures that could involve the use of the devices. GAO also contacted all 12 manufacturers for the power morcellators FDA cleared for the U.S. market.

The Department of Health and Human Services provided technical comments on a draft of this report, which were incorporated as appropriate.

View [GAO-17-231](#). For more information, contact Marcia Crosse at (202) 512-7114 or crosse.m@gao.gov.

MEDICAL DEVICES

Cancer Risk Led FDA to Warn Against Certain Uses of Power Morcellators and Recommend New Labeling

What GAO Found

Between 1991 and 2014, the Food and Drug Administration (FDA)—the federal agency responsible for the oversight of medical devices—cleared 25 submissions for laparoscopic power morcellators for the U.S. market. FDA cleared the submissions for these devices, which cut tissue into small pieces to facilitate removal through small incision sites of gynecological and other types of minimally invasive surgeries, through its premarket notification process. Under this process, established under section 510(k) of the Federal Food, Drug, and Cosmetic Act, FDA reviews information submitted by a device manufacturer and determines whether the new device is substantially equivalent to another legally marketed device, known as a predicate device. In making this determination, FDA assesses whether a device has (1) the same intended use; and (2) the same technological characteristics as a predicate device, or has different technological characteristics but submitted information demonstrates the device is as safe and effective as the predicate device, and does not raise different questions of safety or effectiveness. A device determined to be substantially equivalent is cleared to be marketed. For power morcellators, FDA determined the devices in all 25 of the 510(k) submissions had the same intended use as their predicates, while 6 had new technological characteristics.

Prior to receiving adverse event reports, FDA understood the risk of having an unsuspected cancer that could be spread using a power morcellator as low; in response to such reports, the agency has taken several actions. According to FDA officials, the agency was aware of the potential for power morcellators to spread tissue (cancerous and noncancerous) when the agency cleared the first device in 1991. FDA officials noted that, at the time, the risk of having a type of uterine cancer that can resemble noncancerous uterine tumors, called fibroids, was thought to be low based on available information. After receiving reports in December 2013 about the spread of an unsuspected cancer following the use of power morcellators in surgeries to treat fibroids, FDA estimated the cancer risk to women undergoing these surgeries to be about 1 in 350 for one type of cancer. FDA issued a safety communication in November 2014 warning against certain uses of power morcellators—specifically in treating uterine fibroids. The agency also issued guidance recommending that manufacturers add a boxed warning to their device labeling, which all current manufacturers followed, and conducted inspections to review hospitals' compliance with medical device reporting requirements. As questions remain related to the use of power morcellators, FDA has continued to monitor adverse event reports, among other actions.

Professional societies provided some guidance to physicians regarding the use of power morcellators, while manufacturers of the devices provided instructions and some technical training. According to officials at professional societies that GAO contacted, there are no professional standards specific to the use of power morcellators, but some guidance and educational resources are available for surgical procedures to treat uterine fibroids in which the devices may be used. Training requirements for physicians using power morcellators generally occur at hospitals as part of the processes to ensure that physicians have suitable experience and abilities. Manufacturers provide instructions for use, and some offer technical training that demonstrates device set-up, operation, and cleaning.

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Abbreviations

ABOG	American Board of Obstetrics and Gynecology
ACOG	American Congress of Obstetricians and Gynecologists
FDA	Food and Drug Administration
HHS	Department of Health and Human Services

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February 7, 2017

Congressional Requesters

Americans depend on the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), to oversee the safety and effectiveness of medical devices marketed in the United States. Beginning in late 2013, media reports raised concerns regarding the safety of one particular medical device, a laparoscopic power morcellator, which cuts tissue into small pieces for removal during minimally invasive surgery.¹ Specifically, these reports described the experience of a patient who underwent surgery involving the use of a power morcellator for the treatment of uterine tumors, known as fibroids, which, by definition, are presumed to be noncancerous. However, according to these reports, this patient also had an unsuspected and difficult to diagnose type of cancer and the use of a power morcellator was thought to have resulted in the spreading of cancerous tissue and worsening the likelihood of her long-term survival.

FDA's oversight of medical devices begins before a new device is brought to the market and continues after a device is on the market. For most medical devices that require premarket review, including power morcellators, FDA determines whether they should be allowed to be marketed in the United States through the agency's premarket notification process established under section 510(k) of the Federal Food, Drug, and Cosmetic Act.² Specifically, under this process, FDA reviews information submitted by the device manufacturer (in a 510(k) submission) and determines whether the new device is substantially equivalent to another legally marketed device, known as a predicate device. To be substantially equivalent, a device must (1) have the same intended use as a predicate device; and (2) have the same technological characteristics as the predicate device, or have different technological characteristics but submitted information demonstrates the device is as safe and effective as the predicate device, and does not raise different questions of safety or effectiveness.³ A device determined to be substantially equivalent is

¹Throughout this report, the term "power morcellator" refers to laparoscopic power morcellators used during minimally invasive surgeries only.

²21 U.S.C. § 360(k).

³21 U.S.C. § 360c(i)(1)(A).

cleared to be marketed in the United States. As part of its postmarket oversight efforts, FDA requires medical device manufacturers, importers, and user facilities (such as hospitals) to report events in which a marketed device may have caused or contributed to a death or serious injury, known as an adverse event.⁴ FDA also encourages voluntary reporting of adverse events from healthcare professionals, patients, caregivers, and consumers. FDA received the first adverse event reports describing the spread of cancer after the use of a power morcellator to treat uterine fibroids about the same time the first media reports raising concerns over the use of the devices were published in December 2013.

Given concerns about the safety of power morcellators, you asked us to examine FDA's clearance of the devices for the U.S. market, the agency's response to adverse event reports, and relevant information and training on the use of power morcellators. This report examines

1. the number of 510(k) submissions for power morcellators FDA cleared for the U.S. market, and the extent to which the agency determined the devices had the same intended uses or technological characteristics as predicate devices;
2. FDA's understanding of any concerns with the use of power morcellators to treat uterine fibroids prior to receiving adverse event reports, and what actions the agency has taken in response to these reports; and
3. the professional standards and guidance for physicians regarding the use of power morcellators, and the instructions for use and training provided by device manufacturers.

To determine the number of 510(k) submissions for power morcellators FDA cleared for the U.S. market, and the extent to which the agency determined they had the same intended uses or technological characteristics, we examined information from FDA's publicly available 510(k) database and FDA's files of 510(k) submissions.⁵ The 510(k) database contains information on devices cleared through FDA's 510(k) premarket review process, including the device, the device

⁴A user facility is a hospital, ambulatory surgical facility, nursing home, or outpatient treatment or diagnostic facility that is not a physician's office. Manufacturers and importers are also required to report certain medical device malfunctions.

⁵We examined the number of 510(k) submissions for power morcellators cleared by FDA as of July 2016.

manufacturer's name, the date FDA determined the device was substantially equivalent to a predicate device, and an FDA-assigned product code that can be linked to a medical specialty. We searched the 510(k) database files in order to identify potential power morcellators and then reconciled those identified to a list of power morcellators provided by FDA. To determine the extent to which these devices had the same intended uses and same technological characteristics as predicate devices, we conducted a review of information from FDA's 510(k) submission files in July 2016. During this file review, we collected data concerning the steps FDA officials took to reach a determination that the devices were substantially equivalent to predicate devices. This included the incremental decisions FDA made concerning the intended use and technological characteristics, and in sum, defined the path the FDA reviewers took to reach a determination of substantially equivalent for each submission. We recorded the individual decisions made for each power morcellator, and analyzed the results. In addition, we reviewed relevant FDA policy and guidance documents, and interviewed knowledgeable agency officials regarding the clearance of power morcellators.

To identify FDA's understanding of any concerns regarding the use of power morcellators to treat uterine fibroids prior to receiving adverse event reports, and the actions FDA has taken in response to these reports, we reviewed device labeling for power morcellators, information from FDA's adverse event databases, and FDA documentation regarding agency actions, including policy and guidance documents and safety communications issued. We examined FDA's public adverse event data for reports the agency received from January 1996 through June 2016 to corroborate information we received from FDA on adverse event reports (both the date the agency received the first report and the number of reports received) about the potential spread of cancer following the use of a power morcellator to treat uterine fibroids.⁶ We conducted a literature search for articles regarding the prevalence of uterine cancer and risks of spreading cancer when using a power morcellator to treat uterine fibroids that were published in peer-reviewed journals between January 1980 and

⁶ January 1996 was the earliest that adverse event data were available for our purposes. June 2016 data were the most recently available at the time of our analysis.

March 2016.⁷ We interviewed FDA officials knowledgeable about the agency's understanding of the risk related to power morcellation and FDA's actions in response to adverse event reports involving the spread of cancerous tissue when using a power morcellator. We also contacted officials from 10 professional societies and other stakeholder organizations that have a potential interest in the use of power morcellators. We selected these professional societies and other stakeholders to include organizations (1) that represent member physicians that may use power morcellators to treat uterine fibroids, (2) that accredit individual physicians and hospitals, and (3) that represent device manufacturers. Of the 10, we interviewed officials and/or reviewed information from 6 organizations.⁸ The perspectives of the officials from these selected professional societies and other stakeholder organizations are not generalizable, but they provided insight on these issues.

To identify professional standards and guidance for physicians regarding the use of power morcellators, and the instructions for use and training provided by device manufacturers, we interviewed officials from the selected professional societies and three selected health care providers. We selected health care providers that performed gynecological procedures that could involve the use of a power morcellator, which included two hospitals that had an accredited surgical residency program for the 2016–2017 academic year and a physicians group. The perspectives of the officials from selected health care providers are not generalizable, but provided us with valuable insight on the training requirements for physicians who use power morcellators. We also contacted all 12 manufacturers for the power morcellators FDA cleared for the U.S. market and asked about their instructions for use and training. We received information from three manufacturers. Other

⁷For our literature review, we searched the Embase, MEDLINE, SciSearch, and ProQuest databases using search terms, including those related to cancer, uterine fibroids, and morcellation. Our review focused on articles that had an abstract or executive summary, were published in English, and were published in a peer-reviewed publication. January 1980 was the date used by FDA for a similar literature search. Articles as of March 2016 were the most recently available at the time of our search.

⁸We interviewed or reviewed information from AAGL (formerly known as the American Association of Gynecologic Laparoscopists), the American Board of Obstetrics and Gynecology, the American Congress of Obstetricians and Gynecologists, America's Health Insurance Plans, The Joint Commission, and the Society of Gynecologic Oncology. The Advanced Medical Technology Association, the American Hospital Association, the American Medical Association, and the Medical Device Manufacturers Association told us they did not have additional information on these topics.

manufacturers we contacted did not provide information, citing ongoing litigation involving their power morcellator devices, or that their power morcellators were no longer marketed in the United States, among other reasons.

To assess the reliability of FDA's data on 510(k) submissions and adverse event reports, we reviewed relevant documentation and traced some data to FDA source documentation. On this basis, we determined that these data were sufficiently reliable for our purposes.

We conducted this performance audit from February 2016 to February 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Uterine Fibroids and Treatment

Uterine fibroids are noncancerous growths that develop from the muscular tissue of the uterus. Most women will develop uterine fibroids at some point in their lives, although most cause no symptoms. In some cases, however, uterine fibroids can cause symptoms, including heavy or prolonged menstrual bleeding, pelvic pressure or pain, or frequent urination, requiring medical or surgical therapy.

Treatment for uterine fibroids includes surgical procedures to remove the uterus (**hysterectomy**) or to remove the fibroids (**myomectomy**). These surgical procedures can be done via minimally invasive laparoscopic procedures or through traditional surgical procedures, such as an abdominal hysterectomy. Other treatments for uterine fibroids include, for example, high-intensity focused ultrasound, and drug therapy.

Source: GAO. | GAO-17-231

Power morcellators are medical devices used during laparoscopic (minimally invasive) surgeries. Morcellation refers to the cutting of tissue into smaller fragments for removal from the body. In laparoscopic surgical procedures, morcellation facilitates the extraction of large pieces of tissue through small incisions. Over time, laparoscopic surgeons have applied different manual methods of morcellation using scalpels, forceps, and other tools that require repetitive manual motions, such as twisting. Power morcellators generally use an electromechanical motor to spin a cylindrical blade within a tube for cutting and removing tissue.

Power morcellators can be used during different types of laparoscopic surgeries, including general surgical procedures, such as spleen and liver surgeries; urological surgical procedures, such as kidney removal surgeries; and gynecological surgical procedures. These laparoscopic gynecological procedures include two types of surgeries used to treat uterine fibroids: (1) the removal of the uterus, known as hysterectomy; and (2) the removal of individual fibroids, known as myomectomy. Some women may prefer laparoscopic hysterectomies and myomectomies, because these procedures are associated with such benefits as a shorter post-operative recovery time and, for laparoscopic hysterectomies, a reduced risk of infection compared to open procedures.

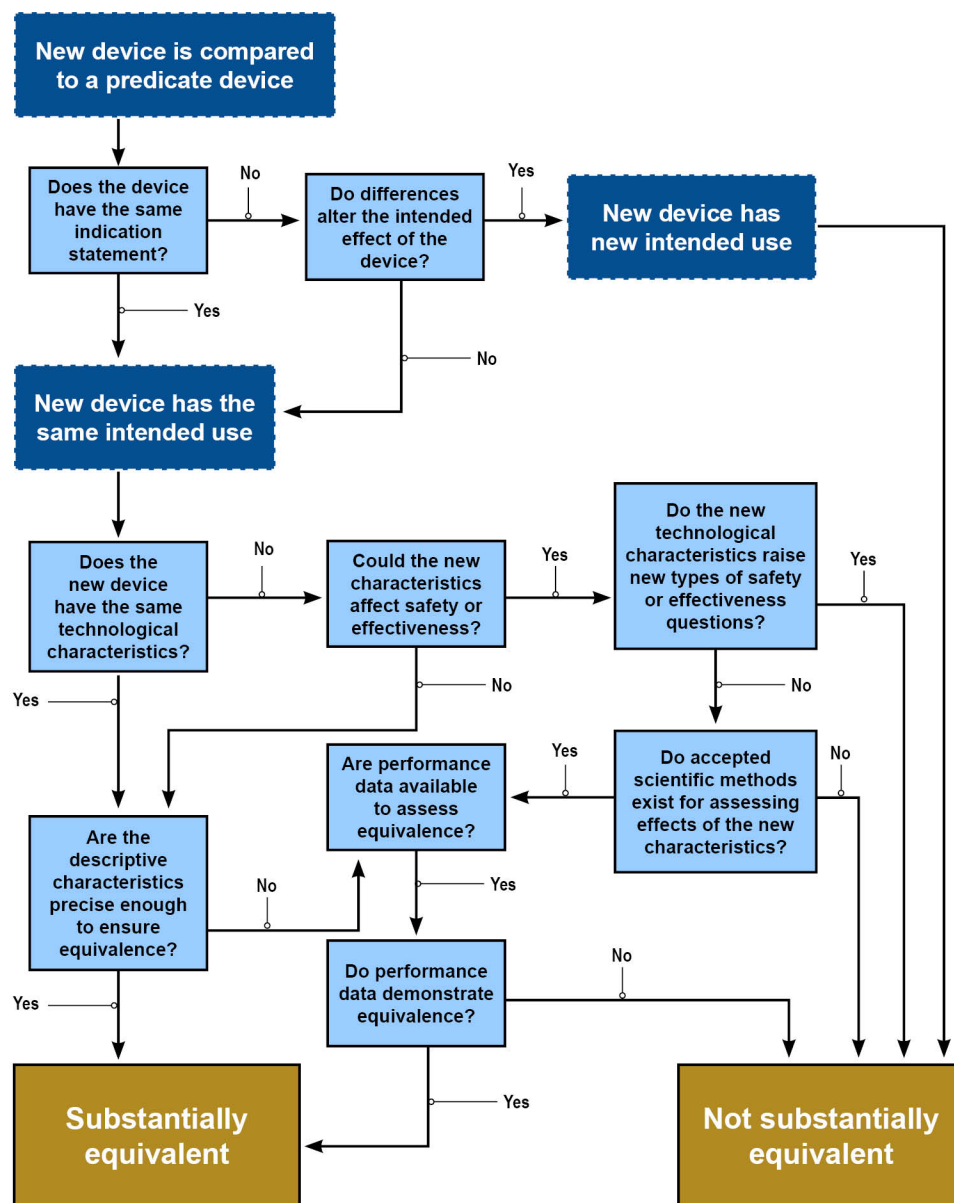
Medical devices, including power morcellators, are regulated by FDA. The agency classified most power morcellators as class II devices, meaning that FDA generally considers them to be higher-risk than class I devices and lower-risk than class III devices.⁹ For most class II devices, FDA determines whether they should be legally marketed in the United States through the agency's 510(k) premarket notification process. Specifically, the device manufacturer through a 510(k) submission must notify FDA at least 90 days before it intends to market a new device and establish that such device is substantially equivalent to a predicate device.¹⁰ To be substantially equivalent, a device must (1) have the same intended use as the predicate device; and (2) have the same technological characteristics as the predicate device, or have different technological characteristics but submitted information demonstrates the device is as safe and effective as the predicate device, and does not raise different questions of safety or effectiveness. Figure 1 shows FDA's decision-making flowchart for its 510(k) premarket notification process in effect when FDA cleared the 510(k) submissions for power morcellators prior to July 2014.¹¹

⁹FDA generally classifies medical devices into one of three classes—class I, II, or III—based on the degree of regulation necessary to provide reasonable assurance of device safety and effectiveness. Class II devices are subject to general controls, such as good manufacturing practices specified in FDA's quality system regulation, and special controls, such as postmarket surveillance, patient registries, or specific FDA guidelines. For some class II devices, including for morcellators, special controls have not been established for the device type. FDA classified one power morcellator device cleared for the U.S. market as a class I device, but the device was never marketed in the United States, according to a letter from the manufacturer to FDA dated March 24, 2015.

¹⁰Under federal regulations, a predicate device can be a device that (1) was legally marketed prior to May 28, 1976; or (2) was marketed on or after May 28, 1976, and was found to be substantially equivalent to a legally marketed device through the 510(k) premarket notification process; or (3) was reclassified by FDA from class III to class II or I. 21 C.F.R. § 807.92 (a)(3) (2016).

¹¹Multiple device models may be marketed under a 510(k) submission. In July 2014, FDA issued guidance updating the decision-making flowchart for the 510(k) premarket notification process. See FDA, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications*, Guidance for Industry and Food and Drug Administration Staff, July 28, 2014, accessed March 11, 2016, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443>.

Figure 1: FDA's Decision-Making Flowchart for the 510(k) Premarket Notification Process Prior to July 2014



Source: GAO analysis of Food and Drug Administration (FDA) documentation. | GAO-17-231

Note: Figure depicts FDA's decision-making flowchart in effect when FDA cleared the 510(k) submissions for laparoscopic power morcellators included in our analysis.

Once a new medical device is on the market, medical device user facilities, manufacturers, and importers must comply with medical device reporting requirements.¹² Under these requirements, these parties must report device-related adverse events, including events that reasonably suggest a device has or may have caused or contributed to a death or serious injury, in a timely manner. For example, user facilities must report such deaths and serious injuries within 10 work days of becoming aware of information reasonably suggesting the device may have caused or contributed to the death or serious injury. Within this time frame, deaths must be reported to both FDA and the manufacturer, if known, and serious injuries must be reported to the manufacturer, or, if the manufacturer is unknown, to FDA.¹³ Consumers and other parties may voluntarily report adverse events directly to FDA. The agency maintains databases that house both mandatory and voluntary reports of device-related adverse events.

While adverse event reports may provide the first signal that a problem exists with a device or its use, or both, FDA and others have reported that information from these reports can be limited.¹⁴ Examples of identified limitations include the following

- **Incomplete or erroneous reporting.** Adverse event reports can include incomplete reporting, where key data are not reported, or erroneous reporting, where the information provided is not accurate.

¹²User facilities include hospitals, ambulatory surgical facilities, and nursing homes. Outpatient diagnostic facilities and outpatient treatment facilities that are not physician's offices are also considered user facilities.

¹³21 C.F.R. § 803.30 (2016). Importers must report device-related deaths and serious injuries to the manufacturer and to FDA no later than 30 calendar days after becoming aware of information reasonably suggesting the device may have caused or contributed to the death or serious injury. Manufacturers must report device-related deaths or serious injuries to FDA no later than 30 calendar days after the day that a manufacturer becomes aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury. Importers and manufacturers also must report certain device malfunctions within the same time frame. 21 C.F.R. §§ 803.40(b), 803.50(a)(2) (2016).

¹⁴See, for example, Food and Drug Administration, Center for Devices and Radiological Health, *Strengthening our National System for Medical Device Postmarket Surveillance*, (Silver Spring, Md.: September 2012), and Institute of Medicine, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years* (Washington, D.C.: National Academies Press, 2011).

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- **Reports that are not timely.** Adverse event reporting does not always reflect real time reporting, as some reports document events that occurred years earlier.
 - **Underreporting.** Adverse events may not always be reported. (See app. I for additional information on medical device reporting requirements.)

In addition to adverse event reporting, FDA conducts other postmarket surveillance activities to obtain information about devices after they are on the market. For example, FDA may order a manufacturer to conduct a postmarket surveillance study if failure of a class II or class III device would be reasonably likely to have serious adverse health consequences.¹⁵

FDA Cleared 25 Power Morcellators; Most Devices Had the Same Intended Use and Technological Characteristics, and Could Be Used for Gynecological Surgeries

FDA documentation shows the agency cleared 25 510(k) submissions for power morcellators to be marketed in the United States between 1991 and 2014.¹⁶ In clearing the first of the 25 power morcellators in 1991, FDA determined the new device was substantially equivalent to an electromechanical system for cutting tissue during minimally invasive surgeries performed on joints, known as an arthroscopic surgical system.¹⁷ (For more information on this predicate device, see app. II.) FDA determined the other 24 power morcellators—the most recent of which was cleared in May 2014—were substantially equivalent to at least one previously cleared power morcellator. We also found that for most power morcellators the documentation we reviewed referenced more than one predicate device. As shown in table 1, the additional devices referenced by manufacturers included other previously marketed devices, such as manual morcellators, forceps, and various accessories used for laparoscopic surgeries. FDA officials stated that the additional devices

¹⁵FDA also may order a manufacturer to conduct a postmarket surveillance study if the device is expected to have significant use in pediatric populations, or the device is intended to be implanted in the human body for more than 1 year or is a life-sustaining or life-supporting device used outside a user facility. 21 U.S.C. § 360l(a)(1)(A).

¹⁶In addition to the 25 510(k) submissions included in our review (those FDA cleared as of July 2016) FDA cleared an additional submission for a power morcellator in October 2016. For more information on this 510(k) submission, see http://www.accessdata.fda.gov/cdrh_docs/pdf16/K161038.pdf (accessed January 23, 2017).

¹⁷References throughout this report to the number of power morcellators relate to the number of unique 510(k) submissions under which FDA cleared power morcellator devices.

referenced likely informed FDA's decision-making for all 25 power morcellators. However, FDA's determinations of substantial equivalence were based on only one predicate device, the arthroscopic surgical system for the first power morcellator cleared and a previously cleared power morcellator for the other 24 devices, according to agency officials.¹⁸ (For more information on each of the 25 power morcellators cleared by FDA, see app. III.)

Table 1: Predicate Devices for the 25 Laparoscopic Power Morcellators Cleared by FDA, 1991 to 2014

FDA documentation of the 25 510(k) submissions for power morcellators referenced previously cleared power morcellators and other legally marketed devices.

Device name (510(k) number ^a)	Date cleared for U.S. market	Devices referenced ^b		Cited as a predicate device or referenced by a subsequent power morcellator
		Previously cleared power morcellator	Other legally marketed device	
Cook Tissue Morcellator (K910939)	6/28/1991		✓✓✓✓	✓✓✓✓
Cook Tissue Morcellator (K925851)	5/21/1993	✓	✓✓✓✓	✓✓✓✓
Cuto Tissue Morcellation System (K932700)	10/15/1993	✓		
KSEA Steiner Electromechanic Morcellator (K946213)	1/27/1995	✓	✓✓✓	✓✓
KSEA Steiner Electromechanic Morcellator (K950339)	4/6/1995	✓	✓✓✓✓	✓✓
KSEA Steiner Electromechanic Morcellator (K946147)	5/25/1995	✓		✓✓✓✓
Surgical Cutter (K955168)	1/22/1996	✓	✓✓✓✓	
FemRx Morcellator System (K963872)	1/17/1997	✓✓✓		✓✓✓✓✓

¹⁸In July 2014, FDA issued guidance regarding the agency's evaluation of substantial equivalence in its 510(k) premarket notification process. Although manufacturers may cite more than one device in their 510(k) submissions, FDA recommends manufacturers clearly identify the primary predicate to which substantial equivalence is being claimed. For its part, FDA guidance states that the agency should clearly document the predicate it relied upon in determining substantial equivalence. FDA considers other devices cited by the manufacturer to be reference devices. In general, reference devices are only considered to support scientific methodology or standard reference values. See Food and Drug Administration, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff*, July 28, 2014, accessed March 11, 2016, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443>.

Device name (510(k) number ^a)	Date cleared for U.S. market	Devices referenced ^b		Cited as a predicate device or referenced by a subsequent power morcellator
		Previously cleared power morcellator	Other legally marketed device	
SEMM Set for Moto-Drive (K960640)	2/14/1997	✓	✓	✓✓✓✓
Coherent Tissue Morcellator Kit (K980079)	4/9/1998	✓✓	✓	✓
Power-Drive (K982515)	1/19/1999	✓✓		✓
Gynecare Laparoscopic Morcellator (K993801)	2/7/2000	✓		✓✓✓✓✓✓✓
KSEA SAWAHLE Electromechanical Morcellator (K010346)	5/2/2001	✓✓	✓	✓✓
KSEA SAWAHLE Electromechanical Morcellator (K011841)	9/10/2001	✓✓✓✓	✓✓	
VersaCut Tissue Morcellator System (K050639)	3/31/2005	✓		✓✓
GYNECARE MORCELLEX Tissue Morcellator (K061050)	7/14/2006	✓✓		✓✓✓
KSEA ROTOCUT G1 Electromechanical Morcellator (K061180)	7/27/2006	✓✓		✓
PKS Plasma Morcellator (K080093)	5/2/2008	✓✓	✓	✓
Morce Power Plus/VarioCarve Morcellator (K080365 ^c)	6/29/2009	✓✓✓✓✓		
GYNECARE MORCELLEX Tissue Morcellator (K100280)	3/24/2010	✓		✓
Trokamed Morcellator (K091010)	3/1/2011	✓✓	✓✓	
SurgiSure Tissue Removal System (K103741)	3/2/2011	✓	✓✓	
LiNA Xcise (K101458)	3/11/2011	✓✓		✓
MORCELLEX SIGMA Generator (K131656)	9/27/2013	✓✓✓✓	✓	
Versacut + Tissue Morcellator (K133272)	5/13/2014	✓✓	✓	

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-17-231

Notes: Each device in the table represents a unique 510(k) submission that FDA identified as a laparoscopic power morcellator cleared by the agency for the U.S. market.

^aThe 510(k) number is a unique control number assigned by FDA to a 510(k) submission.

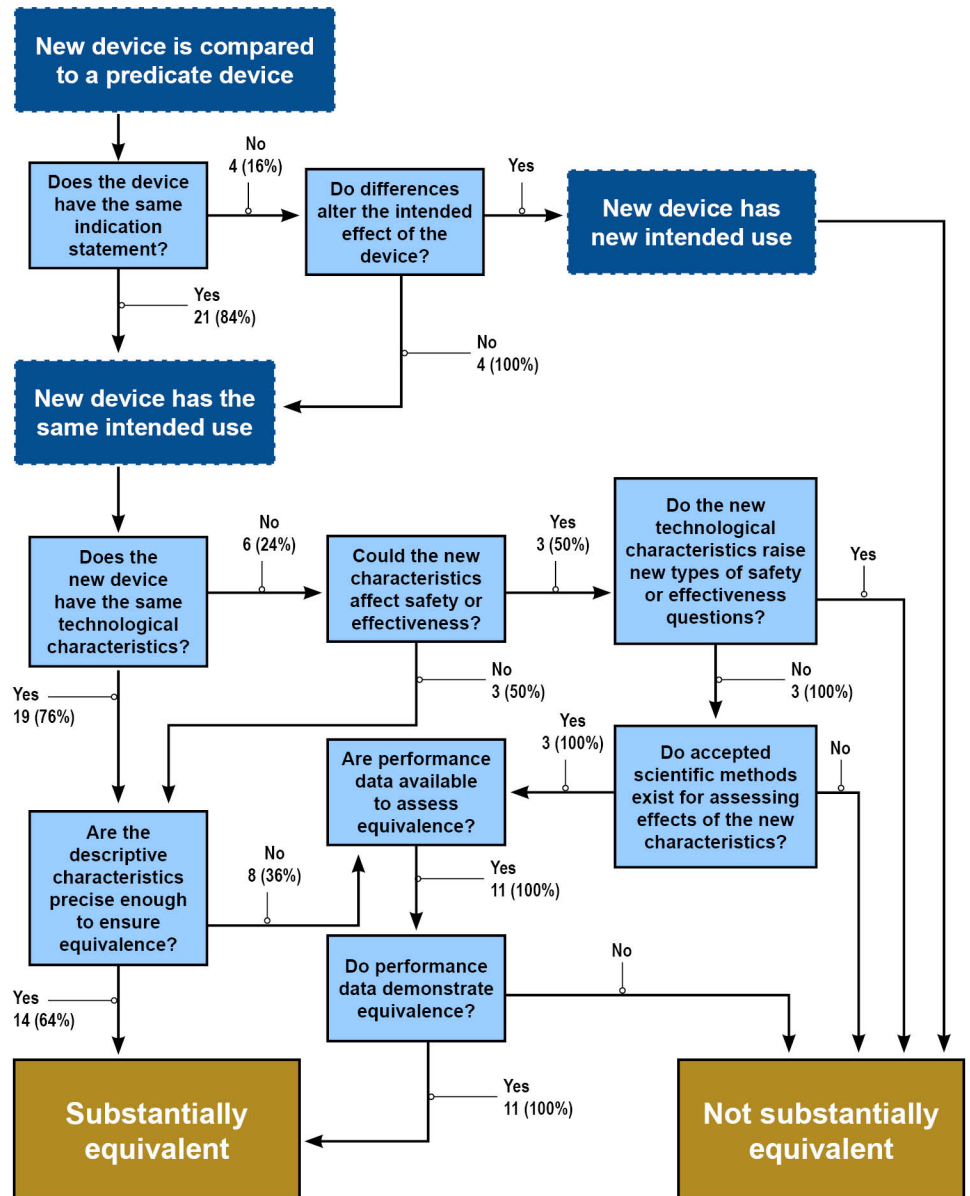
^bEach checkmark refers to a device cited as a predicate or otherwise referenced in the FDA documentation for a 510(k) submission.

^cThis power morcellator was marketed in the United States under two different names by different distributors.

Among the 25 cleared morcellators, we found that FDA determined that all had the same intended use and 19 had the same technological characteristics as their predicate devices; the agency also reviewed performance data for 11 of them. (See fig. 2.)

Figure 2: Number of Laparoscopic Power Morcellators Cleared by FDA Reaching Each Decision Point in FDA's Decision-Making Flowchart for the 510(k) Premarket Notification Process

Of the 25 power morcellators FDA cleared for the U.S. market, the agency determined that 4 had different indication statements and 6 had different technological characteristics.



Source: GAO analysis of Food and Drug Administration (FDA) documentation. | GAO-17-231

Intended Use and Indications for Use

For purposes of determining substantial equivalence, intended use of a device is the general purpose or function as determined based on the product's proposed labeling. Included in the intended use are the indications for use—that is, the disease or condition the device will, among other things, treat or mitigate, including a description of the patient population for which the device is intended. An indication statement is found in a device's proposed labeling.

Source: GAO. | GAO-17-231

In our review of the FDA documentation for power morcellators, we found that the agency determined that all 25 devices had the same intended use as their predicate devices. In making this determination, FDA also determined that 4 power morcellators had different indication statements compared to the predicate devices, but the differences did not alter the intended use of each device. In general, the indication statements for the 4 power morcellators identified new or fewer procedures during which the devices were to be used compared to the predicates. For example, the indication statement for a power morcellator FDA cleared in 2000 specifically identified use in hysterectomies where the predicate's indication statement only identified myomectomies. In another example, the indication statement of a power morcellator cleared in 2011 only identified use in gynecological procedures where the predicate identified general surgical and urological procedures, in addition to gynecological. For all 4 devices, however, FDA determined that the differences in indication statements did not alter the intended effect of the devices or raise new questions of safety or effectiveness, and determined, overall, that the power morcellators had the same intended use as their predicates.

Technological Characteristics

Technological characteristics include materials, design, energy source, and other device features.

Source: Food and Drug Administration guidance. | GAO-17-231

We also found that FDA determined that 19 of the 25 power morcellators had the same technological characteristics as their predicate devices, while 6 devices did not.¹⁹ According to FDA officials, the technological characteristics of these 6 power morcellators that were different included

- the change from the use of a vacuum to suction tissue into the morcellator to the use of forceps to grasp tissue for this purpose;
- the change from single use, disposable body or blade to ones that are reusable;
- the change from a rotary cutting action to one that is reciprocating; and
- the addition of the ability to control suction with a foot switch.

¹⁹To help facilitate FDA's review of technological characteristics, the 510(k) submission may include information identifying similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

In addition, for 11 power morcellators, we found that FDA reviewed performance data.²⁰ These included 3 power morcellators for which FDA determined that different technological characteristics could affect safety and effectiveness, and 8 other power morcellators for which the device description was not sufficient to determine whether the devices were substantially equivalent to predicate devices. For these 11 devices, FDA reviewed performance data—which, according to agency officials, included data such as those from testing the wear of components, electrical safety, and electromagnetic compatibility—and determined that the devices were substantially equivalent to predicates.

Based on our review of FDA documentation, we also found nearly all of the 25 power morcellators were indicated for use in gynecological surgical procedures. We found the indications for use for 14 power morcellators specifically identified laparoscopic gynecological procedures, such as myomectomies and hysterectomies:

- the indications for use of 4 devices identified gynecological procedures only,
- the indications for use of 2 devices identified general surgery and gynecological procedures, and
- the indications for use of 8 devices included general surgery, gynecological, and urological procedures.

For the 11 other devices, 9 power morcellators had indications for use for general surgical procedures, which could include gynecological procedures. (See table 2.)

²⁰When evaluating the technological characteristics of devices, FDA may request performance data when the characteristics are different from the predicate and could affect safety or effectiveness, or when the descriptive information is not precise enough to ensure equivalence.

FDA Understood the Risk of an Unsuspected Uterine Cancer That Could Be Spread When Using a Power Morcellator to be Low; Has Taken Actions in Response to Adverse Event Reports

Table 2: Indications for Use of the 25 510(k) Submissions for Laparoscopic Power Morcellators Cleared by FDA

Indications for use	Number of 510(k) submissions
Laparoscopic general surgical procedures (e.g., the removal of a spleen)	9
Laparoscopic gynecological procedures (e.g., the removal of a uterus or uterine fibroids)	4
Laparoscopic urological procedures (e.g., the removal of a kidney)	2
Laparoscopic general surgical and gynecological procedures	2
Laparoscopic general surgical, gynecological, and urological procedures	8
Total	25

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-17-231

FDA was aware of the potential for spreading tissue when using a power morcellator prior to receiving the first adverse event reports; however, the general understanding was that the risk of an unsuspected cancer that could be spread when using the device was low. In response to adverse event reports, FDA has taken several actions, including estimating cancer risk, warning against certain uses of power morcellators, and recommending new labeling. However, questions remain regarding the use of power morcellators to treat uterine fibroids, and FDA continues to monitor available information.

Prior to Adverse Event Reports, FDA Was Aware of the Potential for Power Morcellators to Spread Tissue, but Understood the Risk of Unsuspected Cancer that Could Be Spread to be Low

FDA officials were aware of the potential for spreading tissue during procedures that involved the use of power morcellators before receiving the first adverse event reports describing the spread of cancerous tissue after the use of a power morcellator to treat uterine fibroids. Specifically, according to FDA officials, the potential for spreading tissue—cancerous or noncancerous—following the use of a power morcellator has been known since the agency cleared the first device in 1991. We found that this awareness was reflected in the labeling for 12 of the 25 devices cleared by FDA. The labeling for these power morcellators recommended the use of a bag when cutting cancerous (diagnosed or suspected) tissue and any other tissue that may be considered harmful if spread.²¹

FDA officials noted that articles reporting the risk of spreading tissue following the use of a power morcellator to treat uterine fibroids were published prior to the agency receiving the first adverse event reports in December 2013. Agency officials, however, noted that at the time, there was no consensus within the clinical community regarding the risk of this occurring, particularly for cancerous tissue. We identified 30 such articles published between 1980 and 2012 that mentioned or concluded a risk of tissue dissemination following the use of a power morcellator, or the need for a physician to remove all fragments of tissue following a surgery. Most of these articles involved case studies or were limited in scope. For example, one case study published in 2010 looked at a single patient who, after undergoing a hysterectomy to treat a uterine fibroid, was found to have a previously unsuspected sarcoma (a type of cancer), and concluded that there is a potential risk of spreading the unsuspected cancer following morcellation.²² None of the articles that we identified estimated the risk of spreading tissue, cancerous or noncancerous, during power morcellation.

²¹While the device labeling recommended using a bag, available data regarding the performance, safety, and effectiveness of bags during laparoscopic morcellation of tissue are limited, according to FDA. In April 2016, FDA permitted the marketing of a new type of device, a tissue containment system that could be used with certain power morcellators during morcellation of noncancerous uterine tissue for certain patients. FDA required the manufacturer of the new tissue containment system to warn patients and health care providers that the system has not been clinically proven to reduce the risk of spreading an unsuspected uterine cancer.

²²See C. Della Badia and H. Karini, "Endometrial Stromal Sarcoma Diagnosed after Uterine Morcellation in Laparoscopic Supracervical Hysterectomy," *Journal of Minimally Invasive Gynecology*, vol. 17, no. 6 (2010).

Uterine Sarcoma

Uterine sarcoma is a cancer of the muscle and supportive tissues of the uterus. Uterine sarcoma is one of two types of uterine cancer (endometrial carcinoma is the other, more common type of uterine cancer). The American Cancer Society estimates that less than 4 percent of uterine cancers are uterine sarcoma. Of the two types of uterine cancer, uterine sarcoma tends to be more aggressive, more difficult to diagnose before surgery, and have worse prognoses. Leiomyosarcoma is a type of uterine sarcoma that, similar to fibroids, develops in the muscular tissue of the uterus. Leiomyosarcoma can resemble a fibroid and, as a result, can be difficult to diagnose before surgery.

Source: GAO. | GAO-17-231

Though the risk of spreading tissue during power morcellation was known, FDA officials stated that prior to December 2013, the general understanding was that the risk of a woman undergoing treatment for fibroids having unsuspected cancer—specifically, a difficult to diagnose cancer called uterine sarcoma—was low. Therefore, the risk of a power morcellator spreading a uterine sarcoma would be expected to be low, as it could be no higher than the risk of having a uterine sarcoma. In addition, FDA officials were not aware of any definitive scientific publications regarding the actual risk of cancer in uterine fibroids (by definition presumed to be noncancerous), which is generally consistent with statements by two professional societies.²³ FDA officials noted that published estimates for an unsuspected cancer (specifically uterine sarcoma) in a woman with a presumed uterine fibroid varied from about 1 in 1,000 women to 1 in about 10,000 women. These estimates of the risk of cancer depended on several factors, including the cancer diagnosis (e.g., uterine sarcoma or a category of uterine sarcoma called leiomyosarcoma), the type of treatment for uterine fibroids (e.g., hysterectomy or myomectomy), or the patient population included in the estimate (e.g., women of reproductive age or women who are older). One 2012 study that examined 1,091 instances of uterine morcellation at one hospital, however, reported that the rate of unsuspected cancer (uterine sarcoma) after laparoscopic morcellation was 9 times higher than the rate quoted to patients at the time (1 in 10,000), and concluded that uterine morcellation carries a risk of spreading unsuspected cancer.²⁴

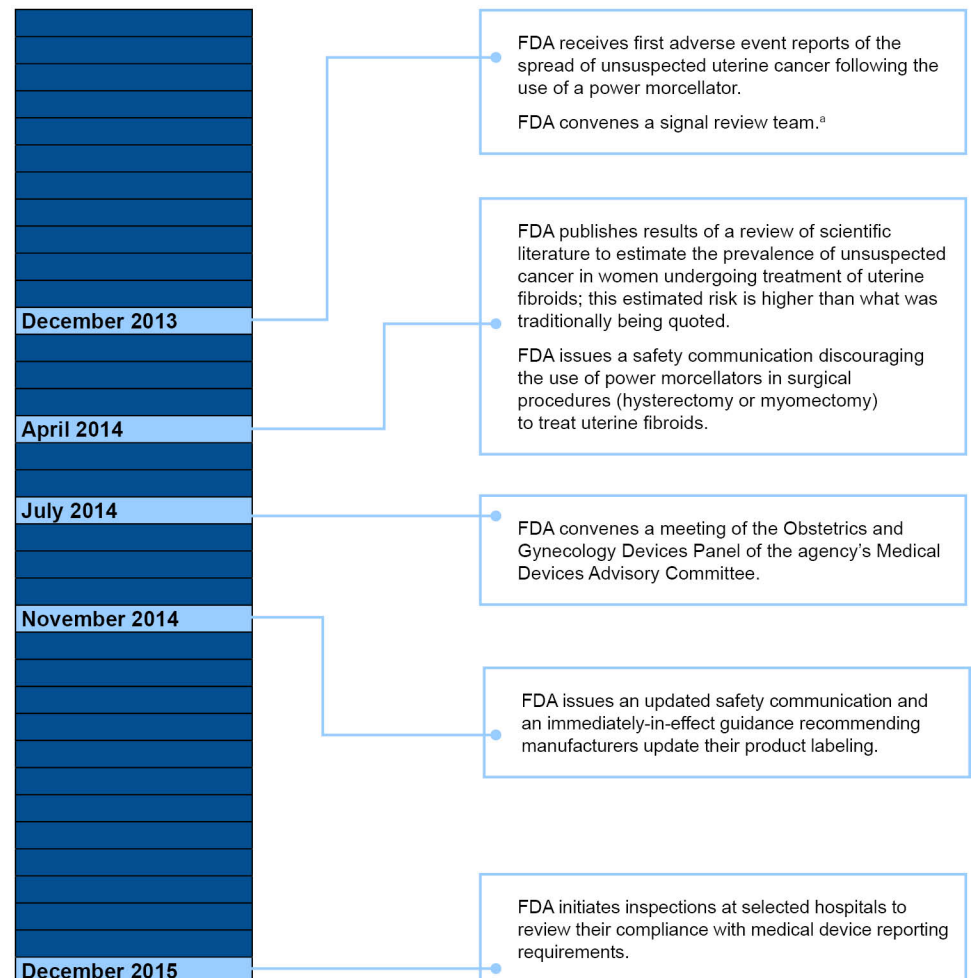
²³For example, a special report from the American College of Obstetricians and Gynecologists published in May 2014 stated that at that time, data were not available to provide an accurate rate of an unsuspected uterine cancer in patients undergoing hysterectomy due to the rarity of uterine cancer, and studies with small sample sizes. See the American College of Obstetricians and Gynecologists, *Power Morcellation and Occult Malignancy in Gynecologic Surgery*, accessed April 28, 2016, <http://www.acog.org/Resources-And-Publications/Task-Force-and-Work-Group-Reports/Power-Morcellation-and-Occult-Malignancy-in-Gynecologic-Surgery>.

²⁴See M. Seidman, T. Oduyebo, M. Muto, C. Crum, M. Nucci, and B. Quade, "Peritoneal Dissemination Complicating Morcellation of Uterine Mesenchymal Neoplasms," *PLoS ONE*, vol. 7, no. 11 (2012).

FDA's Response to First Adverse Event Reports Included Estimating Cancer Risk, Warning Against the Use of Power Morcellators, and Recommending New Labeling

FDA took several actions after receiving the first adverse event reports in December 2013 describing the spread of cancerous tissue after using a power morcellator to treat uterine fibroids. (See fig. 3.) See appendix IV for a more detailed timeline of FDA actions and other events related to power morcellators.

Figure 3: Actions Taken by FDA in Response to First Adverse Event Reports about the Spread of Unsuspected Cancer Following the Use of a Laparoscopic Power Morcellator to Treat Uterine Fibroids



Source: GAO analysis of Food and Drug Administration (FDA) documentation. | GAO-17-231

^aAccording to FDA officials, a signal review team is part of the agency's signal management program, which includes the collection and linking of information from identified sources in determining whether additional agency action related to medical devices is appropriate.

FDA's actions included the following

- **Convening a signal review team.** In December 2013, FDA began forming a signal review team to coordinate and lead the agency's evaluation and response to the potential safety issue related to power morcellators.²⁵ According to FDA officials, the team started meeting weekly and collecting information on the devices, adverse event reports, and scientific literature in January 2014.
- **Estimating the prevalence of cancer in women undergoing surgical treatment for uterine fibroids.** In April 2014, FDA published the results of a review of scientific literature to estimate the prevalence of cancer (specifically sarcoma and leiomyosarcoma) in women undergoing surgical treatment for uterine fibroids.²⁶ Based on this review, FDA estimated that about 1 in 350 women undergoing the surgical procedures of hysterectomy or myomectomy to treat uterine fibroids was at risk for having an unsuspected uterine sarcoma. FDA also estimated that about 1 in 500 such women were at risk for having one certain type of uterine sarcoma, leiomyosarcoma. FDA officials told us that these estimates were significantly higher than what had been traditionally quoted (1 in 1,000 to 1 in 10,000).
- **Issuing an initial safety communication.** In April 2014, FDA issued a safety communication discouraging the use of power morcellators in surgical procedures (hysterectomies and myomectomies) to treat uterine fibroids.²⁷ In discouraging this use, FDA cited the lack of a

²⁵According to FDA officials, a signal review team is part of the agency's signal management program, which includes the collection and linking of information from identified sources in determining whether additional agency action is appropriate related to medical devices. A safety signal is defined as information related to a medical device, which may arise from one or more sources, and suggests a new potential causal association or a new aspect of a known association between a medical device and an adverse event, which may justify or require further evaluation or action from FDA.

²⁶FDA conducted a review of published and unpublished scientific literature from 1980 to 2011. Of the 18 studies identified in that time frame, the agency used 9 studies in developing its estimate. For more information on this review, see Food and Drug Administration, *Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids*, accessed March 1, 2016, <http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM393589.pdf>.

²⁷According to FDA officials, the agency generally issues device safety communications to let health care providers, health care facilities, and/or patients know about postmarket safety findings and recommendations related to those findings. See Food and Drug Administration, *Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication*, April 17, 2014, accessed March 1, 2016, <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm>.

reliable method for predicting whether a woman with uterine fibroids may have an unsuspected cancer; specifically, a uterine sarcoma. The agency also noted that if a power morcellator is used on women with an unsuspected uterine sarcoma, the procedure may spread cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival. The safety communication also recommended that health care providers carefully consider all the available treatment options for women with symptomatic uterine fibroids and thoroughly discuss the benefits and risks of all treatments with patients. FDA also noted that it had instructed manufacturers that produced power morcellators used to treat uterine fibroids to review their device labeling for accurate risk information for patients and providers.

- **Convening a meeting of the Obstetrics and Gynecology Devices Panel of FDA's Medical Devices Advisory Committee.** In July 2014, FDA convened an expert panel and guest speakers to present their views and available data related to the potential power morcellator safety issue.²⁸ The panel discussed patient populations in which power morcellators should not be used, specifically mentioning patients with known or suspected cancer. The panel also discussed mitigation strategies, including the possibility of adding a warning to power morcellator labeling related to the risk of spreading an unsuspected cancer.
- **Issuing guidance.** FDA issued an "immediately in effect" guidance document in November 2014.²⁹ The guidance noted that recent discussions with the patient and clinical communities, as well as the peer-reviewed medical literature, had raised awareness of the risk of

²⁸For more information on the July 2014 meeting of the panel, see <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm404143.htm> (accessed March 9, 2016).

²⁹Guidance documents are documents prepared for FDA staff, regulated industry, and the public that describe the agency's interpretation of or policy on a regulatory issue. The recommendations in the immediately in effect guidance do not establish legally enforceable responsibilities, and the use of the word *should* in agency guidance means that something is suggested or recommended, but not required. The guidance applies to power morcellators with either a general indication or a gynecologic indication, as either may be used in gynecologic laparoscopic procedures; it does not apply to power morcellators specifically indicated only for non-gynecologic surgery. See Food and Drug Administration, *Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators*, November 2014, accessed May 18, 2016, <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf>.

spreading unsuspected cancerous tissue beyond the uterus when power morcellators are used during surgeries intended to treat uterine fibroids. For power morcellators with a general or gynecologic indication for use, the guidance recommended the addition of specific safety statements to the product labeling for laparoscopic power morcellators, including two contraindications and a boxed warning that the use of power morcellators during fibroid surgery may spread cancer.³⁰ (See fig. 4.) FDA also recommended that manufacturers submit their revised labeling language to FDA, as well as to the hospitals and other facilities that had previously purchased power morcellators. We found that the manufacturers of the 10 power morcellators with indications for use for general surgical or gynecological procedures marketed as of November 2016 followed the recommendation, providing FDA with updated labeling.³¹ Information provided by FDA indicated that manufacturers also contacted hospitals and other user facilities that purchased their power morcellators, providing the updated labeling and instructing them to switch out any old labeling. Half of the manufacturers also instructed the user facilities to mail back a receipt of acknowledgement regarding the safety alert to the manufacturer.

Figure 4: FDA's Recommended Boxed Warning for Laparoscopic Power Morcellators, November 2014

WARNING: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

Source: Food and Drug Administration (FDA). | GAO-17-231

³⁰Contraindications describe situations in which a device should not be used because the risk of use clearly outweighs any possible benefit. FDA recommended that labeling include a statement that power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain cancerous tissue. A warning is used to alert the reader about a situation which, if not avoided, could result in death or serious injury, or may also describe potential serious adverse reactions and safety hazards. The designation of a hazard alert as a "warning" is reserved for the most significant problems. If a problem may lead to death or serious injury, FDA may expect the manufacturer to highlight the warning by placing it in a box.

³¹Seven different manufacturers made the 10 power morcellators. See appendix III for additional information.

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- **Issuing an updated safety communication.** At the same time it issued guidance in November 2014, FDA issued an updated safety communication warning against the use of power morcellators in the majority of women undergoing surgery (hysterectomy or myomectomy) to treat uterine fibroids.³² This safety communication recommended that doctors thoroughly discuss the benefits and risks of all treatments with their patients. The updated safety communication also specified that FDA considers the spread of unsuspected cancer when using a power morcellator for hysterectomy or myomectomy to treat uterine fibroids as a serious injury, which is a reportable adverse event under the agency's medical device reporting requirements.
 - **Inspecting selected user facilities for compliance with adverse event reporting.** In December 2015, FDA initiated inspections at selected hospitals to review their compliance with medical device reporting requirements, which specify that hospitals and other user facilities must report certain device-related events to FDA and to manufacturers when the manufacture is known.³³ These inspections included five hospitals that, according to FDA officials, were chosen because there were reports of adverse events at these facilities related to the spread of uterine cancer from the use of power morcellators.³⁴ FDA identified significant deviations from medical device reporting requirements at these hospitals based on its review of the inspection evidence. FDA investigators' observations included user facilities' failure to report adverse events within required time frames or to establish and maintain files for medical device

³²This safety communication superseded the April 2014 safety communication. See Food and Drug Administration, *UPDATED Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication*, November 24, 2014, accessed March 1, 2016, <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm>.

³³User facilities must report death-related adverse events to FDA no more than 10 work days after they become aware of information that reasonably suggests that a device may have caused or contributed to a death. They must also submit these reports to the device manufacturer, if the manufacturer is known. In addition, user facilities are required to submit reports of serious injuries to manufacturers within 10 work days. If the manufacturer is not known, the serious injury report must be submitted to FDA. 21 C.F.R. § 803.30 (2016).

³⁴FDA inspects manufacturers' compliance with medical device reporting requirements (e.g., reporting deaths and serious injuries to FDA) as part of routinely scheduled and directed inspections of device manufacturers. See appendix I for additional information on these inspections.

reporting—that is, adverse event reports.³⁵ The agency determined that corrective action plans presented by two of the five hospitals were adequate, and according to FDA officials, the agency worked with the three other hospitals to help ensure appropriate corrective actions were taken.

Questions Remain Regarding the Use of Power Morcellators to Treat Uterine Fibroids, and FDA Continues to Monitor Available Information

Questions remain regarding the use of power morcellators in the treatment of uterine fibroids, which include varying stakeholder opinions regarding the risks related to the use of power morcellators. For example, FDA officials noted there was limited information available to assess how the risk of spreading cancerous tissue is affected when the morcellation is performed using a power morcellator or through manual morcellation (e.g., using a scalpel). Similarly, officials from one professional society also stated that they were not aware of any reliable data showing that power morcellation spreads tissue any worse than other morcellation techniques. In addition, professional societies have questioned or noted concerns with FDA's estimate of the risk of cancer (uterine sarcoma) in women who undergo surgical treatment of uterine fibroids, citing limitations related to FDA's methodology. One professional society's open letter to FDA included concerns regarding the keywords FDA officials used to find the studies included in their estimate, stating that those keywords may have limited the number of studies used to develop the agency's estimate. The letter also asserted that FDA's estimate was higher than a more appropriate estimated risk of uterine cancer of about 1 in 1,500 to 1 in 2,000.³⁶ FDA officials have acknowledged limitations, such as the small number of studies, in their estimate, but stated that estimates in more recently representative published studies have generally been consistent with the agency's estimate.

Continuing questions also include the long-term effects of FDA's guidance on patients, according to the stakeholders we interviewed. Two professional societies we contacted have expressed concern that FDA's decision to discourage the use of power morcellators in laparoscopic surgeries (hysterectomies and myomectomies) to treat uterine fibroids limits women's health options. According to officials from the two societies, the reduction or elimination of laparoscopic surgery using a

³⁵These observations are made by the FDA representative(s) during the inspections and do not represent the agency's final determination regarding the facility's compliance.

³⁶See <http://www.aagl.org/wp-content/uploads/2015/12/open-letter-to-FDA-re-morcellation-with-cities.pdf> (accessed April 14, 2016).

power morcellator to treat uterine fibroids—in response to FDA’s safety communication and guidance—may lead to an increased use of abdominal hysterectomies, a surgical procedure that typically does not involve the use of power morcellators, but is associated with other risks. One professional society noted that abdominal hysterectomies require larger incisions, slower recovery time, and present the patient with higher mortality rates and complications than laparoscopic hysterectomies. However, FDA officials noted that one 2016 study reported a decline in the use of power morcellators in hysterectomies since the agency issued its November 2014 guidance, and found no increase in complications from abdominal hysterectomies.³⁷

While these questions remain, FDA officials stated that the agency continues to review scientific literature regarding the use of power morcellators to treat uterine fibroids as new studies have been conducted since 2014. We found more than 50 articles on the risk of uterine cancer in women or the use of morcellation in women undergoing gynecologic surgeries like hysterectomy and myomectomy—including peer-reviewed articles, case studies, and opinion pieces—that have been published since December 2013.

FDA also continues to monitor available adverse event information regarding the use of power morcellators, while acknowledging the limitations of the available information. FDA reported that, as of September 2016, the agency had identified 285 adverse event reports about the spread of an unsuspected cancer following the use of a power morcellator. According to FDA officials, the majority (over 88 percent) of these reports were mandatory reports submitted by manufacturers. The remainder were voluntary reports from patients and their families, as well as physicians (about 10 percent) and mandatory reports from hospitals and other user facilities (less than 2 percent). According to FDA officials, of the 285 adverse event reports regarding power morcellators and the spread of unsuspected cancer that the agency received through

³⁷The study reported a decline in the use of power morcellators in hysterectomies since FDA issued its guidance in November 2014—from 13.5 percent to under 3 percent of minimally invasive hysterectomies. This study reviewed data on approximately 203,000 women who underwent a hysterectomy (with approximately 58 percent undergoing a minimally invasive hysterectomy) from 2013 to the first quarter of 2015 from more than 500 hospitals across the United States, and approximately 15 percent of hospitalized patients. See J. Wright, L. Chen, W. Burke, et al. “Trends in Use and Outcomes of Women Undergoing Hysterectomy With Electric Power Morcellation,” *JAMA*, vol. 316, no. 8 (2016).

September 2016, 5 were related to events occurring after FDA issued its guidance and updated safety communication in November 2014.³⁸ FDA officials noted, however, the limitations in the current, passive, medical device reporting system, which relies on people to identify that a harm occurred or a risk is present, recognize that the harm or risk is associated with the use of a particular device, and take the time to report it. For power morcellators, officials from three health care providers (two hospitals and one physician group) that we spoke to stated that prior to November 2014, physicians would likely not have considered the spreading of an unsuspected cancer following the use of a power morcellator as a reportable adverse event, because the device would have performed as intended (e.g., cutting and extracting tissue). FDA's inspections of manufacturers of power morcellators and hospitals that use them have also identified issues related to medical device reporting of adverse events. (See app. I for more information on FDA inspections related to medical device reporting.)

Recognizing the limitations in its current postmarket surveillance activities, the agency reported plans to generate better information in the future. For example, in October 2016, the agency reported plans to work with hospitals to identify a system that quickly identifies life-threatening problems caused by medical devices. FDA officials also noted they will continue to review new technologies, such as morcellation containment systems, and work on a national registry to collect data on the treatment of fibroids.³⁹ In addition, FDA is working to establish a National Evaluation System for health Technology to more efficiently generate better evidence for medical device evaluation and regulatory decision-making.

³⁸According to FDA officials, media attention or litigation surrounding a safety issue, like with power morcellators, can lead to an increase in reports being submitted to manufacturers for adverse events that happened in the past.

³⁹FDA permitted the marketing of the first tissue containment system for use with certain power morcellators in April 2016. See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494650.htm> (accessed November 27, 2016). FDA's Center for Devices and Radiological Health is a participant in the stakeholder advisory group for the COMPARE-UF registry to evaluate the effects of treatments for uterine fibroids. The registry expects to enroll about 10,000 women in a project phase that began in December 2015. According to FDA, the agency hopes to leverage this registry for further information related to the surgical treatment of fibroids.

Professional Societies Provided Guidance Regarding the Use of Power Morcellators, While Device Manufacturers Provided Instructions and Technical Training

The professional societies we contacted did not have any professional standards or training requirements for physicians specifically regarding the use of power morcellators, but some societies issued guidance to physicians related to procedures that could involve the use of power morcellators. The training requirements for physicians performing procedures like hysterectomies are typically determined at the hospital level. All power morcellator manufacturers provided instructions for use, and some offered technical training.

Professional Societies Do Not Have Specific Standards on the Use of Power Morcellators, but Some Provided Guidance on Procedures That Could Involve the Device

Officials from three professional societies we contacted—AAGL (formerly the American Association of Gynecologic Laparoscopists), the American Board of Obstetrics and Gynecology (ABOG), and the American Congress of Obstetricians and Gynecologists (ACOG)—stated that there are no professional standards issued by their societies that apply to member physicians specifically regarding the use of power morcellators. ABOG, which certifies obstetricians and gynecologists in the United States, does not deal directly with training recommendations or requirements related to the use of power morcellators. AAGL and ACOG, which are professional societies representing member physicians; The Joint Commission, which accredits hospitals; and three health care providers, which included two hospitals and a physician group, we contacted stated that training requirements for physicians performing specific procedures, such as procedures to treat uterine fibroids, are generally governed by hospital credentialing and privileging.⁴⁰

⁴⁰The Joint Commission issued an advisory on safety and quality issues in November 2014 that states that one of the actions health care organizations can take is to ensure appropriate training and credentialing for minimally invasive surgery, including use of the power morcellators, and that privileges should be based on training, experience, and documented competency. See http://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Eight_Nov_2014_FINAL_2.PDF (accessed April 21, 2016). The credentialing process determines whether physicians have suitable abilities and experience to provide care or services for a health care organization. The privileging process determines which health care services a physician should be allowed to provide.

While the professional societies that we contacted did not set standards or requirements for using power morcellators, some provided guidance and educational resources for their members on the procedures that could involve the use of power morcellators. For example, in May 2014, the American College of Obstetricians and Gynecologists (ACOG's companion organization) published a special report on clinical recommendations and scientific issues related to hysterectomies or myomectomies.⁴¹ This special report touched on topics related to proper diagnosis and evaluation before a hysterectomy or myomectomy, the use of a bag during morcellation in gynecologic surgery, and patient counseling and informed consent information that should be discussed with a patient if a power morcellator is being considered for use during the procedure.

Officials from the three health care providers that we interviewed indicated that physicians may receive training in using power morcellators during their medical residency (for example, if their attending physician used the device). The officials also noted that, after completing their medical residency, physicians who want to use power morcellators for laparoscopic surgery would likely seek out training, such as individual training from another physician with experience using the device. According to health care provider officials, physicians' privileges to perform laparoscopic hysterectomies and myomectomies could be part of broader privileges—for example, they said that some hospitals may grant permission for a physician to use a power morcellator as part of a general list of procedures for gynecologists, or a hospital could require specific permission for use of the device.

Manufacturers Provided Instructions and Offered Technical Training on the Use of Power Morcellators

All of the 25 power morcellators cleared by FDA included instructions from the manufacturers for using the device, and some of the manufacturers offered technical training for physicians. FDA regulations require that the labeling for a prescription device like a power morcellator, which is not safe for use except under the supervision of a licensed practitioner, must provide information on the device's use, including

⁴¹In general, the American College of Obstetricians and Gynecologists focuses on physician and patient education and clinical guideline development, among other things, while ACOG advocates for members' professional interests and improvements in women's health. See <http://www.acog.org/Resources-And-Publications/Task-Force-and-Work-Group-Reports/Power-Morcellation-and-Occult-Malignancy-in-Gynecologic-Surgery> (accessed April 8, 2016).

precautions under which practitioners can use the device safely and the purpose for which the device is intended.⁴² We found the labeling for the 25 power morcellators included instructions for use (submitted by the manufacturers to FDA as part of the agency's premarket review of the devices), which provided information such as device assembly, use, disassembly, and safety information. One power morcellator manufacturer that responded to our request for information stated that it has a standard procedure to review the instructions for use with new users of its power morcellator. In addition to providing instructions for use, two manufacturers that provided us with information also offered technical training to physicians on their power morcellators, such as demonstrating how to set-up or operate their devices. FDA does not require manufacturers to provide clinical training for power morcellators, that is, training on the actual morcellation of tissue during a surgical procedure. One manufacturer we spoke to stated that clinical training is typically part of a surgeon's accredited residency and fellowship program.

⁴²21 C.F.R. § 801.109 (2016).

Agency Comments

We provided a draft of this report to the Secretary of Health and Human Services. HHS provided technical comments that were incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.



Marcia Crosse
Director, Health Care

List of Requesters

The Honorable Louise Slaughter
Ranking Member
Committee on Rules
House of Representatives

The Honorable Rosa L. DeLauro
Ranking Member
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
House of Representatives

The Honorable Ralph Abraham, M.D.
House of Representatives

The Honorable Lou Barletta
House of Representatives

The Honorable Anna G. Eshoo
House of Representatives

The Honorable Brian Fitzpatrick
House of Representatives

The Honorable Doug LaMalfa
House of Representatives

The Honorable Rick Larsen
House of Representatives

The Honorable Stephen Lynch
House of Representatives

The Honorable Bill Pascrell, Jr.
House of Representatives

The Honorable Jan Schakowsky
House of Representatives

The Honorable Chris Smith
House of Representatives

Appendix I: Food and Drug Administration's Adverse Event Reporting System and Process for Monitoring Compliance

The Food and Drug Administration (FDA) uses information gathered through adverse event reporting to monitor and track potential safety issues associated with medical devices after they are marketed in the United States. According to FDA, adverse event reports are best used for two purposes. First, they are used to capture qualitative snapshots of adverse events for a particular device or device type, such as the types of malfunctions or clinical events, or both, associated with the device. Second, they are used to detect safety signals, such as identifying unexpected events associated with a particular device or device type.¹

Adverse event reports are submitted to FDA through mandatory and voluntary sources. Mandatory adverse event reporting by medical device importers, manufacturers, and user facilities enables FDA to obtain specific safety data related to medical devices from these reports.² FDA regulations require medical device importers, manufacturers, and user facilities that become aware of information suggesting that a device may have caused or contributed to a death or serious injury to provide information to FDA.³ Manufacturers and importers also must report certain device malfunctions—manufacturers must report the information to FDA and importers must report the information to the manufacturer.⁴ (See table 3 for summaries of these reporting requirements.) FDA also encourages healthcare professionals, patients, caregivers, and

¹According to FDA officials, a safety signal is information related to a medical device, which may arise from one or more sources, and suggests a new potential causal association or a new aspect of a known association between a medical device and an adverse event, which may justify or require further evaluation or action from FDA.

²A user facility is a hospital, ambulatory surgical facility, nursing home, or outpatient treatment or diagnostic facility that is not a physician's office.

³Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of failure, malfunction, improper or inadequate design, manufacture, labeling, or user error. Serious injuries are injuries or illnesses that are life-threatening, result in permanent impairment of a body function or permanent damage to a body structure, or necessitate medical or surgical intervention to preclude permanent impairment of a body function or damage to a body structure.

⁴Malfunctions are defined as the failure of a device to meet its performance specifications or otherwise perform as intended.

**Appendix I: Food and Drug Administration's
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consumers to submit voluntary adverse event reports or problems with medical devices.⁵

Table 3: Summary of Adverse Event Reporting Requirements for Medical Device Importers, Manufacturers, and User Facilities

What to report	To whom	When
Importers		
Deaths and serious injuries ^a	FDA and the manufacturer	Within 30 calendar days of becoming aware of an event
Malfunctions ^b	Manufacturer	Within 30 calendar days of becoming aware of an event
Manufacturers		
Deaths, serious injuries, and malfunctions	FDA	Within 30 calendar days of becoming aware of an event (or within 5 work days upon FDA's request)
Deaths, serious injuries, and malfunctions requiring remedial action	FDA	Within 5 work days of becoming aware of an event
Supplemental reports to provide new, changed, or corrected information for a previously submitted report	FDA	Within 30 calendar days of receipt of the information
User facility^c		
Death	FDA and manufacturer, if manufacturer is known	Within 10 work days
Serious injury	Manufacturer, or FDA if manufacturer unknown	Within 10 work days
Annual summary of death and serious injury ^d	FDA	January 1 for the preceding year

Source: Food and Drug Administration (FDA). | GAO-17-231

^aSerious injuries are injuries or illnesses that are life-threatening, result in permanent impairment of a body function or permanent damage to a body structure, or that necessitate medical or surgical intervention to preclude permanent impairment of a body function or damage to a body structure.

^bMalfunctions are defined as the failure of a device to meet its performance specifications or otherwise perform as intended.

^cA user facility is a hospital, ambulatory surgical facility, nursing home, or outpatient treatment or diagnostic facility that is not a physician's office.

^dUser facilities are required to file annual reports that summarize their adverse event reports.

⁵In addition to FDA's regular adverse event reporting system, the agency launched the Medical Product Safety Network (MedSun) in 2002 to collect mandatory adverse event reports from a limited number of hospitals and user facilities. The primary goal of MedSun is to enable FDA to work collaboratively with specific device-user facilities in the clinical community to identify, understand, and solve problems with the use of devices.

According to FDA officials, while the agency has enforcement authority over mandatory adverse event reporting by user facilities, the agency has generally focused its enforcement resources on manufacturers—which are required to investigate each reportable event.⁶ According to FDA officials, of the 2,185 device inspections conducted in fiscal year 2015, 875 included a review of medical device reporting. Of these inspections, FDA reported that the agency found 284 to have inspection observations related to medical device reporting requirements. Of the 12 manufacturers of power morcellator medical devices, FDA reported inspecting 11 of them in the past 5 years (including inspections for devices other than power morcellators).⁷ As a result of these inspections, FDA reported identifying problems related to medical device reporting such as manufactures not reporting adverse events within required time frames or not implementing medical device reporting procedures.⁸ For three manufacturers, the inspections resulted in FDA issuing warning letters that cited, among other things, violations of medical device reporting requirements.

FDA may also inspect user facilities' compliance with medical device reporting requirements, for example, in situations where the user facility perspective is essential to understanding the public health issue. Recently, in light of several high-profile device safety issues occurring in hospitals, the agency initiated inspections at 17 hospitals in December 2015. According to the director of FDA's Center for Devices and Radiological Health, these hospitals were chosen because there were reports of events at these facilities related to the spread of uterine cancer from the use of power morcellators or the spread of infections associated

⁶When evaluating the potential safety issues associated with power morcellators, in April 2014, FDA sent letters to registered power morcellator manufacturers requesting information on any complaints the manufacturers received related to power morcellators, and requested information on any adverse event reports the manufacturers may have submitted to FDA. The letters also strongly encouraged manufacturers to review their power morcellator device labeling.

⁷According to FDA officials, surveillance based inspectional assignments are dependent upon factors, including operational status, as maintained in the agency's registration and listing database. FDA officials indicated that the 12th power morcellator manufacturer was not inspected, because it has not maintained an active registration and listing status with FDA, since 2011.

⁸According to FDA, as of September 2016, the agency conducted 58 inspections of 11 manufacturers of power morcellators since 2011—most of which were specific to devices other than power morcellators—and found problems with medical device reporting during 10 of the inspections.

with another device called a duodenoscope.⁹ The director noted that while these events appeared to be the kind that would have fallen under the agency's medical device reporting requirements, the agency did not see corresponding adverse event reports submitted to FDA's adverse event report database. He further reported that from these inspections, the agency learned several things, including

- Some hospitals did not submit required reports for deaths or serious injuries related to devices used at their facilities; and in some cases, they did not have adequate procedures in place for reporting device-related deaths or serious injuries to FDA or to the manufacturers. Based on the number of user facilities in the United States and the number of reports FDA receives, the agency believes that these hospitals are not unique, in that there is limited to no reporting to FDA or to the manufacturers at some hospitals.
- Hospital staff often were not aware of nor trained to comply with all of FDA's medical reporting requirements.

The director also noted that FDA wants to work with hospitals to address issues of limited or nonreporting, and to work with hospitals to get the real-world information FDA needs. For example, following the inspections, FDA held regulatory meetings with certain hospitals to help identify corrective actions. In addition, FDA hosted a public workshop in December 2016 to discuss how to improve hospitals' role in monitoring medical device safety.¹⁰

⁹See Food and Drug Administration, *Infections Associated with Reprocessed Duodenoscopes*, accessed October 24, 2016, <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/reprocessingofreusablemedicaldevices/ucm454630.htm>. FDA documentation shows that inspections at five hospitals were initiated specifically in response to reports of events related to the spread of uterine cancer from the use of power morcellators.

¹⁰See Food and Drug Administration, *Public Workshop - The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation: Harnessing the Digital Revolution for Surveillance*, December 5, 2016, accessed December 28, 2016, <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm506670.htm>.

Appendix II: History of Predicate Devices for the First Laparoscopic Power Morcellator

In clearing the first laparoscopic power morcellator in 1991 through the 510(k) premarket notification process, the Food and Drug Administration (FDA) determined the device was substantially equivalent to an electromechanical system for cutting tissue during minimally invasive surgeries performed on knees and other joints.¹ According to FDA officials, this device, known as an arthroscopic surgical system, was one of a number of devices cited by the manufacturer in the 510(k) submission; however, the agency based its determination of substantial equivalence primarily on the arthroscopic surgical system. As shown in table 4, FDA documentation shows that the device can be traced back to a surgical system also used for cutting during knee surgeries that FDA determined in 1978 to be substantially equivalent to a predicate device that was marketed prior to the enactment of the Medical Device Amendments of 1976 (May 28, 1976).²

Table 4: Predicate Device for the First Laparoscopic Power Morcellator Cleared by FDA and Related Devices

Device name (510(k) number ^a)	Date cleared	Devices referenced ^b	Description
PacesetterTM 3500 Arthroscopic Surgical System (K880150)	March 1988	K833587, K820367, and K771218	Electromechanical system for cutting tissue during minimally invasive surgeries on the knee and other joints.
Disposable Arthroscopy Blade (K833587)	November 1983	K771218	Disposable, single-use, blade assembly used in arthroscopic surgical systems.
Intra-articular Surgical System (K820367)	May 1982	K771218 and BPI-NS Driver ^c	Electromechanical system for cutting and removing tissue during minimally invasive surgeries on the knee and other joints.
Intra-articular Surgical System (K771218)	February 1978	BPI-NS Driver ^c	Battery-powered device for cutting tissue during minimally invasive surgeries on the knee.
BPI-NS Driver ^c	Not applicable	Not applicable	Battery-powered device for cutting the skull during surgeries on the skull.

Source: GAO analysis of Food and Drug Administration (FDA) documentation. | GAO-17-231

^aThe 510(k) number is a unique control number assigned by FDA to a 510(k) submission.

^bDevices referenced identifies devices cited as a predicate or otherwise referenced in the FDA documentation for a 510(k) submission.

^cAccording to FDA officials, the BPI-NS Driver was on the market prior to the enactment of the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976), and, therefore, this device did not require FDA premarket review under the 510(k) process.

¹Under the 510(k) premarket notification process, FDA determines whether a new device is substantially equivalent to another legally marketed device, known as a predicate device; those devices found to be substantially equivalent are cleared for the U.S. market.

²Devices on the market prior to the enactment of the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976), did not require FDA premarket review under the 510(k) process.

Appendix III: General Characteristics of the 25 510(k) Submissions for Laparoscopic Power Morcellators Cleared by the Food and Drug Administration

Between 1991 and 2014, the Food and Drug Administration cleared 25 laparoscopic power morcellators to be marketed in the United States. Figure 5 shows the device type, medical specialty, and indications for use for 11 power morcellators still being marketed in the United States in November 2016.¹ Figure 6 provides the same information for the other 14 devices that were no longer being marketed in November 2016.

¹One of the 11 power morcellators on the market at that time was only indicated for urological procedures and therefore FDA's November 2014 guidance on recommended labeling for devices with indications for use in general and/or gynecological surgical procedures did not apply to this particular power morcellator.

Appendix III: General Characteristics of the 25
510(k) Submissions for Laparoscopic Power
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Figure 5: Device Type, Medical Specialty, and Indications for Use for 11 510(k) Submissions for Laparoscopic Power Morcellators Marketed in United States, November 2016

Manufacturer name/Device name	510(k) number ^a	Device type (Product code ^b)					Medical specialty			Indications for use	
		Electrosurgical, cutting and coagulation and accessories (GEI)	Laparoscope, general and plastic surgery (GCU)	Laparoscope, gynecologic and accessories (HET)	General & Plastic Surgery	Gastroenterology/Urology	Obstetrics/Gynecology	General surgery	Gynecological surgery	Urological surgery	
Gyrus ACMI											
PKS Plasma Morcellator	K080093	✓		✓	✓		✓	✓	✓	✓	
Karl Storz Endoscopy-America											
KSEA SAWAHLE Electromechanical Morcellator	K010346		✓	✓		✓	✓	✓	✓		
KSEA SAWAHLE Electromechanical Morcellator	K011841		✓			✓				✓	
KSEA ROTOCUT G1 Electromechanical Morcellator	K061180		✓	✓		✓	✓	✓	✓	✓	
LiNA Medical Aps											
LiNA Xcise	K101458			✓			✓		✓		
Lumenis											
Coherent Tissue Morcellator Kit	K980079		✓			✓		✓			
VersaCut Tissue Morcellator System	K050639		✓			✓		✓			
Versacut + Tissue Morcellator	K133272		✓			✓		✓			
Nouvag											
Morce Power Plus ^c	K080365			✓			✓	✓	✓		
Promex^d											
Surgical Cutter	K955168	✓			✓			✓			
Trokamed											
Trokamed Morcellator	K091010		✓	✓		✓	✓	✓	✓	✓	

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-17-231

Note: Each device row represents a unique 510(k) submission that FDA identified as a laparoscopic power morcellator cleared by the agency as of July 2016 and marketed in the United States as of November 2016.

^aThe 510(k) number is a unique control number assigned by FDA to a 510(k) submission.

^bThe product code identifies the generic category of a device. FDA assigns product codes based upon the medical device product classification designated under 21 C.F.R. pts. 862-892.

^cThis morcellator was one of two models marketed in the United States by different distributors—Richard Wolf and Olympus. According to the Olympus, the VarioCurve Morcellator has not been distributed in the United States since 2011. The device type, medical specialty, and indications for use for the VarioCurve Morcellator were the same those for the Morce Power Plus.

^dPromex was the manufacturer for this device at the time FDA cleared the 510(k) submission (K955168); the device is currently marketed by Nico Corporation as the NICO Myriad.

Appendix III: General Characteristics of the 25
510(k) Submissions for Laparoscopic Power
Morcellators Cleared by the Food and Drug
Administration

Figure 6: Device Type, Medical Specialty, and Indications for Use for 14 510(k) Submissions for Laparoscopic Power Morcellators No Longer Marketed in the United States, November 2016

Manufacturer name/Device name	510(k) number ^a	Device type (Product code ^b)					Medical specialty			Indications for use	
		Electrosurgical, cutting and coagulator and accessories (GEI)	Laparoscope, general and plastic surgery (GCU)	Laparoscope, gynecologic and accessories (HET)	General & Plastic Surgery	Gastroenterology/Urology	Obstetrics/Gynecology	General surgery	Gynecological surgery	Urological surgery	
Cook Urological											
Cook Tissue Morcellator	K910939	✓			✓			✓			
Cook Tissue Morcellator	K925851	✓			✓			✓			
Ethicon ^c											
FemRx Morcellator System ^d	K963872		✓	✓		✓	✓	✓	✓	✓	
Gynecare Laparoscopic Morcellator	K993801			✓			✓	✓	✓	✓	
GYNECARE MORCELLEX Tissue Morcellator	K061050			✓			✓	✓	✓	✓	
GYNECARE MORCELLEX Tissue Morcellator	K100280			✓			✓	✓	✓	✓	
MORCELLEX SIGMA Generator	K131656			✓			✓	✓	✓	✓	
Interlace Medical											
SurgiSure Tissue Removal System	K103741		✓			✓		✓			
Karl Storz Endoscopy-America											
KSEA Steiner Electromechanic Morcellator	K946147			✓			✓		✓		
KSEA Steiner Electromechanic Morcellator	K946213		✓			✓		✓			
KSEA Steiner Electromechanic Morcellator	K950339		✓			✓				✓	
Linvatec											
Cuto Tissue Morcellation System	K932700	e			✓			✓			
WISAP											
Power-Drive	K982515			✓			✓		✓		
SEMM Set for Moto-Drive	K960640			✓			✓		✓		

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-17-231

Note: Each row represents a unique 510(k) submission that FDA identified as a laparoscopic power morcellator cleared by the agency, but no longer marketed in the United States as of November 2016.

^aThe 510(k) number is a unique control number assigned by FDA to a 510(k) submission.

^bThe product code identifies the generic category of a device. FDA assigns product codes based upon the medical device product classification designated under 21 C.F.R. pts. 862-892.

^cEthicon initiated a worldwide withdrawal of its power morcellators on July 30, 2014.

^dFDA data identifies Gynecare Innovation Center as the manufacturer of this device. According to an FDA official, Gynecare Innovation Center is a division of Ethicon.

**Appendix III: General Characteristics of the 25
510(k) Submissions for Laparoscopic Power
Morcellators Cleared by the Food and Drug
Administration**

^aWhen clearing this 510(k) submission, FDA assigned a product code for surgical instrument motors and accessories/attachments (GEY). According to FDA officials, the assignment should have been electrosurgical, cutting and coagulation device and accessories (GEI), but no action was taken to correct the product code, because the manufacturer asserted that the device was never marketed and formally withdrew the 510(k) in March 2015.

Appendix IV: Detailed Timeline of Events Related to Laparoscopic Power Morcellators

Table 5 shows key events related to laparoscopic power morcellators and the actions the Food and Drug Administration has taken in relation to safety concerns of the spread of unsuspected uterine cancer following the use of power morcellators in the treatment of uterine fibroids.

Table 5: Timeline of Key Events Related to Laparoscopic Power Morcellators

Date	Key event
March 1988	The Food and Drug Administration (FDA) clears the Pacesetter™ 3500 Arthroscopic Surgical System—a predicate device for the first power morcellator—for the U.S. market.
June 1991	FDA clears the Cook Tissue Morcellator—the first power morcellator—for the U.S. market.
May 1995	FDA clears the KSEA Steiner Electromechanic Morcellator—the first power morcellator with indications for use for gynecologic laparoscopic procedures—for the U.S. market. The indications for use specifically identified the removal or morcellation of uterine fibroids.
February 2000	FDA clears the Ethicon Gynecare Laparoscopic Morcellator—the first power morcellator with indications for use that identified hysterectomies (among other procedures)—for the U.S. market.
November 2013	FDA receives the first notification of an event where the use of a power morcellator during surgery to treat uterine fibroids may have spread an unsuspected uterine cancer.
December 2013	The Wall Street Journal publishes an article on the same event. FDA receives the first adverse event reports of the spread of unsuspected uterine cancer following the use of a power morcellator. In response, the agency convenes a signal review team to coordinate and lead FDA's evaluation and response to the potential power morcellator safety issue.
April 2014	FDA publishes the results of a review of scientific literature published since 1980, and finds that the risk of having an unsuspected and difficult to diagnose type of cancer, uterine sarcoma, is about 1 in 350 for women undergoing the surgical procedures of hysterectomy or myomectomy to treat uterine fibroids. FDA also estimated that the risk for having a specific type of sarcoma called leiomyosarcoma was about 1 in 500 among such women. FDA issues a safety communication that (1) reports the higher rate of unsuspected uterine cancer in women who undergo treatment for uterine fibroids (about 1 in 350), and (2) discourages the use of power morcellators in surgical procedures (hysterectomy or myomectomy) to treat uterine fibroids. FDA also sends letters to power morcellator manufacturers strongly recommending the review of product labeling and coordination with the agency to ensure that such labeling addresses the estimated risk.
July 2014	FDA convenes a meeting of the Obstetrics and Gynecology Devices Panel of FDA's Medical Devices Advisory Committee to solicit stakeholder input and available data related to the potential power morcellator safety issue. One manufacturer of power morcellators initiates a voluntary withdrawal of its power morcellators from the U.S. market.
November 2014	FDA issues an updated safety communication and an "immediately in effect" guidance recommending manufacturers include a boxed warning and additional contraindications in their product labeling. FDA's guidance states that manufacturers should implement these labeling recommendations and that within 120 days, a manufacturer with an existing 510(k) clearance should (1) add the contraindications and boxed warning to their labeling; (2) submit revised labeling to FDA; and (3) provide updated labeling to purchasers for power morcellators that have already been distributed. The safety communication also states that FDA considers the spread of an unsuspected cancer following the use of a power morcellator to treat uterine fibroids as a serious injury reportable under adverse event reporting regulations.

**Appendix IV: Detailed Timeline of Events
Related to Laparoscopic Power Morcellators**

Date	Key event
December 2015	<p>FDA initiates inspections at selected hospitals to review their compliance with medical device reporting requirements. These inspections included five hospitals that, according to FDA, were chosen because there were reports of adverse events at these facilities related to the spread of uterine cancer from the use of power morcellators.</p> <p>Enrollment begins in the COMPARE-UF registry phase, which is expected to enroll about 10,000 women and evaluate the effects of treatments for uterine fibroids.</p>
April 2016	<p>FDA permits the marketing of a new type of device, a tissue containment system that could be used with certain power morcellators during morcellation of noncancerous uterine tissue for certain patients. FDA required the manufacturer of the new tissue containment system to warn patients and health care providers that the system has not been clinically proven to reduce the risk of spreading an unsuspected uterine cancer.</p>

Source: GAO. | GAO-17-231

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7114 or crossem@gao.gov

Staff Acknowledgments

In addition to the contact named above, Kim Yamane (Assistant Director), Aaron Holling (Analyst-in-Charge), Jazzmin Cooper, and Kate Tussey made key contributions to this report. Also contributing were Leia Dickerson, Sandra George, Drew Long, and Vikki Porter.

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