What GAO Found

In fiscal years 2003 through 2007, as part of its premarket review to determine whether devices should be permitted to be marketed in the United States, FDA

- reviewed 13,199 submissions for class I and II devices via the 510(k) process, clearing 11,935 (90 percent) of these submissions;
- reviewed 342 submissions for class III devices through the 510(k) process, clearing 228 (67 percent) of these submissions; and
- reviewed 217 original and 784 supplemental PMA submissions for class III devices and approved 78 percent and 85 percent, respectively, of these submissions.

Although Congress envisioned that class III devices would be approved through the more stringent PMA process, and the Safe Medical Devices Act of 1990 required that FDA either reclassify or establish a schedule for requiring PMAs for class III device types, this process remains incomplete. GAO found that in fiscal years 2003 through 2007 FDA cleared submissions for 24 types of class III devices through the 510(k) process. As of October 2008, 4 of these device types had been reclassified to class II, but 20 device types could still be cleared through the 510(k) process. FDA officials said that the agency is committed to issuing regulations either reclassifying or requiring PMAs for the class III devices currently allowed to receive clearance for marketing via the 510(k) process, but did not provide a time frame for doing so.

Class III Device Submissions with FDA Review Decisions in Fiscal Years 2003 through 2007, by FDA Review Process and Review Decision

<table>
<thead>
<tr>
<th>Number of submissions</th>
<th>510(k)</th>
<th>Original PMA</th>
<th>Supplemental PMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not cleared/not approved</td>
<td>228</td>
<td>170</td>
<td>664</td>
</tr>
<tr>
<td>Cleared/approved</td>
<td>114</td>
<td>47</td>
<td>120</td>
</tr>
</tbody>
</table>

n = 342
n = 217
n = 784

85% approved

Source: GAO analysis of FDA data.

Notes: 510(k) includes traditional and abbreviated 510(k) submissions. Supplemental PMA includes certain types of submissions for changes to devices that were previously approved through the PMA process. Not cleared/not approved includes 510(k) submissions that were denied or other (e.g., withdrawn) and PMAs that were withdrawn or otherwise not approved.