RL I

30525

DECISION

THE COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

FILE: B-217291 **DATE:** February 26, 1985

MATTER OF: Impact Instrumentation, Inc.

DIGEST:

1. Agency may award to firm which does not have Food and Drug Administration (FDA) permission to market solicited surgical device at the time of award where solicitation provision which requires needed FDA approval does not require that offeror have approval prior to award.

2. Determination by Food and Drug Administration that a manufacturer of a surgical device can commercially market its device is not subject to review by GAO.

3. Contention that contractor is supplying nonconforming products is a matter of contract compliance and administration not for review under GAO Bid Protest Procedures.

Impact Instrumentation, Inc. (Impact), protests the award of a contract to H.C.H. Products, Inc. (HCH), the low acceptable offeror under request for proposals (RFP) No. DLA120-84-R-0398 issued by the Defense Personnel Support Center (DPSC), Defense Logistics Agency (DLA).

The solicitation was for 187 surgical suction and pressure apparatuses for field use. Impact contends that HCH did not meet the RFP requirement that the product offered meet the requirements of the Federal Food, Drug and Cosmetic Act (FFDCA) and implementing regulation for approval of surgical devices. Furthermore, Impact alleges that the item HCH has offered does not meet the RFP specifications and thus HCH intends to supply a nonconforming product.

We deny the protest in part and dismiss it in part.

The RFP contained the following specification:

> "Federal Food, Drug and Cosmetic Act. If the product covered by this document has been determined by the U.S. Food and Drug Administration to be under its jurisdiction, the offeror/contractor shall comply, . . . with the requirements of the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder . . . ."

DLA reports that the surgical device solicited is covered by the FFDCA, and thus the premarket notification procedures, 21 C.F.R. part 807 (1984), issued by the Food and Drug Administration (FDA) apply to this device. This regulation essentially requires the manufacturer of a surgical device to submit to the FDA information concerning the manufacturing concern and the product it proposes to market. The notification to the FDA is called section 510(k) notification, and, after notification, the FDA renders a decision as to whether the product may be marketed.

The record contains a letter dated August 10, 1984, received September 25, from HCH to the FDA providing the requisite 510(k) notification. By letter dated October 11, 1984, the FDA determined that HCH's device was "substantially equivalent" to a device marketed prior to the Medical Devices Amendments to the FFDCA. Thus, FDA advised HCH that it could market in interstate commerce its device consistent with the provisions of the FFDCA. DPSC awarded the contract to HCH on August 22, 1984. The first required delivery date was December 21, 1984.

Impact contends that DSPC could not award this contract to HCH because HCH was not in compliance with the FFDCA with regard to marketing this device at the time of award. DLA contends that HCH was determined to be a responsible offeror with the ability to perform the contract and had the necessary 510(k) authorization from FDA prior to performance of this contract, which was all that was necessary under the RFP.

In our view, the solicitation provision at issue does not require that a firm have the 510(k) approval at the time of award, and DLA properly could make the responsibility determination that HCH would comply with the FDA regulations prior to performance of the contract. Cove Shipping, Inc., B-215864, Oct. 19, 1984, 84-2 C.P.D. ¶ 423. Thus, in essence, Impact's protest constitutes a challenge against HCH's ability to comply with the solicitation requirement concerning FDA approval. An offeror's ability to fulfill a contract requirement constitutes a matter of responsibility.

As a prerequisite to award, a contracting officer must make an affirmative determination of responsibility. Hooper Goode, Inc., B-209830, Mar. 30, 1983, 83-1 C.P.D. ¶ 329. Such a determination was made here and our Office does not review an affirmative determination of responsibility unless there is a showing of possible fraud or the solicitation contains definitive responsibility criteria which allegedly have not been met. Ace Van & Storage Company, B-210083, Dec. 28, 1982, 82-2 C.P.D. ¶ 586. Neither exception has been alleged here. We note further that HCH received its FDA 510(k) approval more than 2 months before the first required delivery. See Propper Manufacturing Co., Inc., B-208035, Mar. 22, 1983, 83-1 C.P.D. ¶ 279.

Impact also questions FDA's 510(k) approval of HCH's product. In this connection, Impact alleges that HCH did not file its request for 510(k) approval in a timely fashion and that the FDA based its approval on inadequate information. Impact thus concludes that DPSC will not receive the item called for by DPSC under the RFP specifications. The propriety of the FDA's granting of 510(k) approval for HCH's surgical device is not reviewable by our Office. The issues raised by Impact concerning FDA 510(k) approval of HCH's product and HCH's compliance with the FFDCA is within the jurisdiction of the FDA. See Propper Manufacturing Co., B-208035, supra; Paramex Labs, Inc., B-205826, Mar. 16, 1982, 82-1 C.P.D. ¶ 249. In this connection, we note that Impact has filed a request with the FDA to reconsider the FDA's 510(k) approval of HCH's product.

Finally, to the extent Impact is alleging that the product HCH is delivering does not meet contract requirements, this protest is dismissed. An allegation that an awardee might provide noncomforming products is a matter of contract compliance and administration, which are the responsibility of the contracting agency, not our Office under our bid protest function. Lion Brothers Company, Inc., B-212960, Dec. 20, 1983, 84-1 C.P.D. ¶ 7.

Seymour Efros
for Harry R. Van Cleve
General Counsel