January 2009

MEDICAL DEVICES

FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process

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Highlights

Highlights of GAO-09-190, a report to congressional addressees

Why GAO Did This Study

The Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) is responsible for oversight of medical devices sold in the United States. Regulations place devices into three classes, with class III including those with the greatest risk to patients. Unless exempt by regulation, new devices must clear FDA premarket review via either the 510(k) premarket notification process, which determines if a new device is substantially equivalent to another legally marketed device, or the more stringent premarket approval (PMA) process, which requires the manufacturer to supply evidence providing reasonable assurance that the device is safe and effective. Class III devices must generally obtain an approved PMA, but until FDA issues regulations requiring submission of PMAs, certain types of class III devices may be cleared via the 510(k) process. The FDA Amendments Act of 2007 mandated that GAO study the 510(k) process. GAO examined which premarket review process—510(k) or PMA—FDA used to review selected types of device submissions in fiscal years 2003 through 2007. GAO reviewed FDA data and regulations, and interviewed FDA officials.

What GAO Recommends

GAO recommends that FDA expeditiously take steps to issue regulations for class III device types currently allowed to enter the market via the 510(k) process by requiring PMAs or reclassifying them to a lower class. HHS agreed with GAO's recommendation.

To view the full product, including the scope and methodology, click on GAO-09-190. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

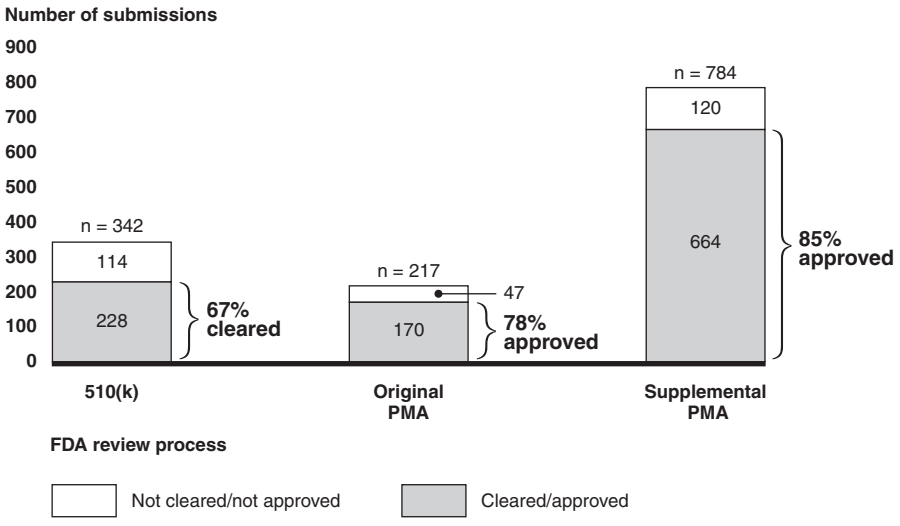
What GAO Found

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



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.