

Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for overseeing medical devices sold in the United States. In general, new devices are subject to FDA review via either the 510(k) premarket notification process, which determines if a 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. FDA also has broad responsibilities for postmarket surveillance of devices, including oversight of recalls. A recall involves the correction or removal of a product from the market and is an important remedial action that can mitigate the risks associated with a defective or unsafe medical device. In recent years, GAO has identified a wide variety of concerns related to FDA's ability to fulfill its mission of protecting the public health and added FDA's oversight of medical products, including devices, to its list of high-risk areas.

This statement provides an update on FDA's actions in response to a recommendation made in GAO's report, *Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process* ([GAO-09-190](#), January 15, 2009). It also contains preliminary information on FDA's oversight of medical device recalls. Because of the preliminary nature of this work, GAO is not making recommendations at this time.

View [GAO-11-556T](#) or key components. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

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MEDICAL DEVICES

FDA's Premarket Review and Postmarket Safety Efforts

What GAO Found

FDA has begun to take steps to address GAO's 2009 recommendation about high-risk devices that are allowed to enter the U.S. market through the less stringent 510(k) process, but progress has been limited. High-risk devices include those which are implantable or life sustaining. In 2009, GAO recommended that FDA expeditiously take steps to issue regulations for the device types classified as high risk that are currently allowed to enter the market via the 510(k) process. Since then, FDA has set strategic goals to address these device types, but has issued a final rule regarding the classification of only one device type. As of April 1, 2011, FDA's action on the 26 remaining types of high-risk devices was incomplete. Thus, these types of devices—such as automated external defibrillators and implantable hip joints—can still enter the U.S. market through the less stringent 510(k) process. GAO found that, since its report was issued in January 2009, FDA has cleared at least 67 510(k) submissions that fall within these high-risk device types. FDA has taken some additional steps to enhance premarket device safety since GAO's 2009 report was issued—for example, it commissioned the Institute of Medicine to conduct an independent review of the premarket review process—but it is too early to tell whether any forthcoming changes will enhance public health.

GAO's preliminary analysis shows that, from 2005 through 2009, firms initiated 3,510 voluntary medical device recalls, an average of just over 700 per year. Although FDA maintains extensive information on each recall, it has not been routinely analyzing recall data that would allow it to explain trends in recalls over time, thus missing an opportunity to proactively identify and address the risks presented by unsafe devices. GAO's preliminary work also identified several gaps in the medical device recall process that limited recalling firms' and FDA's abilities to ensure that the highest-risk recalls were being implemented in an effective and timely manner. GAO found that firms frequently were unable to correct or remove all devices subject to the highest-risk recalls. GAO's preliminary findings indicate that FDA lacks clear guidance for overseeing recalls which has led to inconsistencies in FDA's assessments of whether individual recalls were implemented effectively. Consequently, FDA officials examining similar situations sometimes reached opposite conclusions regarding whether recalls were effective. In addition, FDA had not established thresholds for assessing whether firms effectively completed recalls by correcting or removing a sufficient number of recalled devices. Further, GAO determined that FDA's decisions to terminate completed recalls—that is assess whether firms had taken sufficient actions to prevent a reoccurrence of the problems that led to the recalls—were frequently not made within its prescribed time frames. Finally, GAO found that FDA did not document its justification for terminating recalls. Taken together, GAO's preliminary work suggests that the combined effect of these gaps may increase the risk that unsafe medical devices could remain on the market.