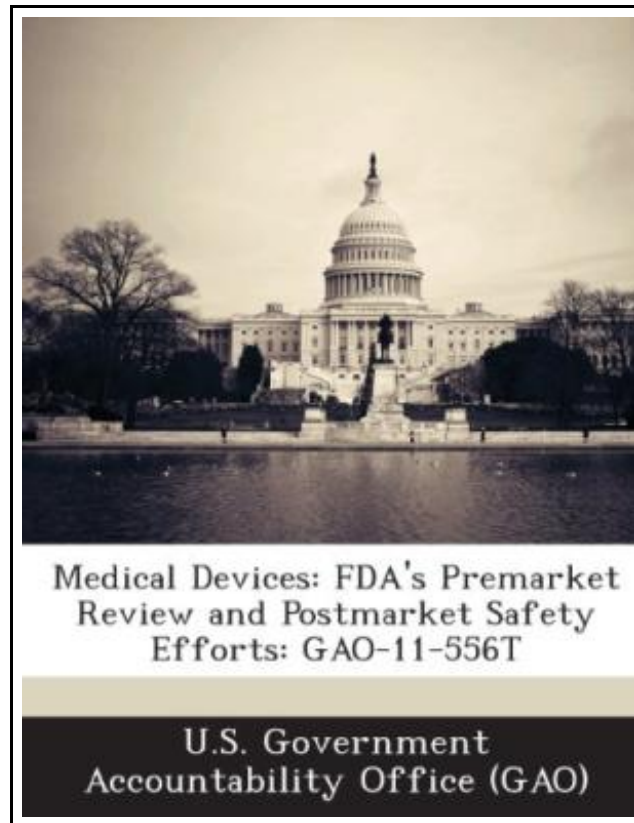


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Bibliogov. Paperback. Book Condition: New. This item is printed on demand. Paperback. 26 pages. Dimensions: 9.7in. x 7.4in. x 0.1in. The Food and Drug Administration (FDA) is responsible for overseeing medical devices sold in the United States. In 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 FDAs ability to fulfill its mission of protecting the public health and added FDAs oversight of medical products, including devices, to its list of high-risk areas. This statement provides an update on FDAs actions in response to a recommendation made in GAOs 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 FDAs oversight of medical device recalls. Because of the preliminary nature of this work, GAO is not making recommendations at this time. This item ships from La Vergne, TN. Paperback.



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