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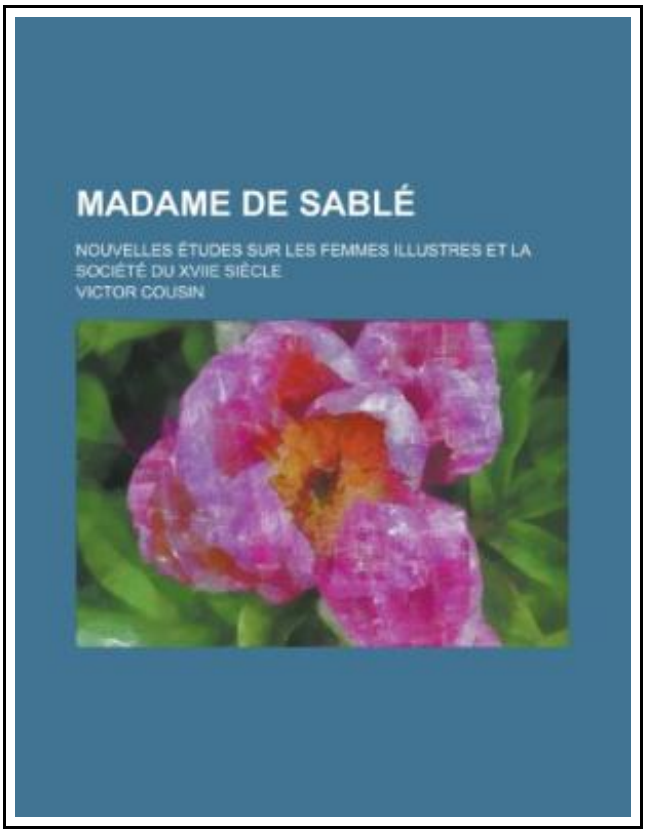

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RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 24 pages. Original publisher: Washington, D. C. : U. S. Govt. Accountability Office, 2009 OCLC Number: (OCoLC)430340142 Subject: Medical instruments and apparatus industry -- United States. Excerpt: . . . Congress envisioned that all class III devices would eventually be required to undergo premarket review through the more stringent PMA process, we believe it is imperative that FDA take immediate steps to address the remaining class III device types that may still enter the market through the less stringent 510 (k) process by requiring PMAs for or reclassifying them. In April 2009, FDA took what it termed the first step towards completing the review of Class III device types predating the 1976 law, as was recommended by the U. S. Government Accountability Office (GAO) in a January 2009 report to Congress. Specifically, FDA announced that it was requiring manufacturers of 25 types of class III medical devices marketed prior to 1976 to submit safety and effectiveness information to the agency by August 7, 2009, so that it may evaluate the risk level for each device 25 type. In the Federal Register notice announcing the requirement, FDA stated that once the safety and effectiveness information was submitted, the agency would be able to determine which device types would be required to undergo the agencys most stringent premarket review process. FDAs requirement that manufacturers submit safety and effectiveness information is an essential initial step toward implementing our recommendation and fully implementing the law. However, FDA did not specify a time frame for how quickly it will review the submitted information, determine whether to reclassify the device types, and require PMAs for those that remain in class III. It should be noted, however, that while the PMA...

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