

## FDA to Review Medical Devices Marketed Prior to 1976

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Washington, DC - The FDA today announced that manufacturers of 25 types of medical devices marketed prior to 1976 must submit safety and effectiveness information to the agency so that it may evaluate the risk level for each device type. Devices found by the FDA to be of high risk to consumers will be required to undergo the agency's most stringent premarket review process.

These 25 device types, which are listed in the Federal Register announcement posted today, were marketed in the U.S. prior to the Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1976. That law authorized the FDA to review new medical devices. Today's announcement is 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.

The FDA classifies medical devices into three categories according to their level of risk. Class III devices represent the highest level of risk and generally require a showing of safety and effectiveness before they may be marketed. Class III devices include heart valves and intraocular lenses. Class I and Class II devices pose lower risks and include devices such as adhesive bandages and wheelchairs. Most Class II devices and some Class I devices are marketed after submission of premarket notifications establishing their substantial equivalence to legally marketed devices that do not require premarket approval.

After Congress enacted the medical device law in 1976, the FDA classified these 25 device types into Class III (premarket approval). Under the law, these devices were not immediately required to undergo the premarket approval process. The law required the FDA to issue a rule subjecting the devices to that requirement. Until that time, new devices within those device types have been cleared through the premarket notification process, in which the agency determines whether they are substantially equivalent to legally marketed devices not requiring premarket approval. Devices that present a new intended use or include new technology that presents new questions of safety or effectiveness may not be found substantially equivalent and require premarket approval.

"We are taking the necessary steps to complete this very complex process while continuing to protect public health by thoroughly reviewing and evaluating all medical device submissions presented to the agency," said Daniel G. Schultz, M.D., director of the FDA's Center for Devices and Radiological Health. "New premarket notification submissions for devices of these 25 types will continue to receive an appropriate level of scrutiny to ensure safety and effectiveness."

As of 1994, there were approximately 149 Class III, pre-1976 types of medical devices that had not yet been subject to premarket approval. Since then, the FDA has made significant progress in reviewing and issuing new regulations for all but 27 of those device types, including the review of 55 types since January 2000. (The FDA has already initiated this process for two device types, which will be completed separately.)

Manufacturers of the 25 remaining device types must submit the requested information within 120 days. The FDA will review the submitted data and, based on the risk level, issue regulations for each device type that either will require manufacturers to submit premarket approval applications or will re-classify the devices into Class I or Class II.