FDA Issues Order Requiring Safety and Effectiveness Information from Older Medical Devices

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On April 9, 2009, the Food and Drug Administration (FDA, or the Agency) issued an order that requires manufacturers of 25 high risk Class III medical devices, which were marketed before 1976 but have not yet undergone the premarket approval (PMA) review process, to submit safety and effectiveness information to the Agency. 74 Fed. Reg. 16214-17 (Apr. 9, 2009). The Agency will use this information to determine, for each device, whether the device's classification should be revised to require a PMA application or notice of completion of a Product Development Protocol (PDP)—the most stringent premarket review processes for medical devices—or whether the device should be reclassified as a lower-risk class I or II device.

Background

Pursuant to the Medical Device Amendments of 1976, the FDA classifies medical devices into three regulatory classes based on the level of risk the devices pose to consumers. Pub. L. 94-295 (May 28, 1976). Class I and II devices are those with lower levels of risk than Class III and they are subject to less stringent controls—Class I is subject to only "general controls," such as registration with the FDA, while class II devices are subject to "special controls," which can include submission of a 510(k) premarket notification. Class III devices are the highest risk devices and thus, they must show evidence of safety and effectiveness through premarket approval.

The medical devices identified in today's Order were classified after 1976 as high risk Class III devices, but were not immediately required to submit PMA applications. Many devices, referred to as "preamendment devices," have been reviewed and subsequently sold based on a premarket notification process, known as 510(k), which requires only that the device be "substantially equivalent" to other cleared or approved devices. Specifically, 228 class III submissions were cleared by the FDA through this 510(k) process between 2003 and 2007 for device types marketed before 1976, or device types "substantially equivalent" to them, which had not undergone the PMA process. GAO-09-190 (January 2009).

FDA Responds to GAO Findings

Today's order is effectively in response to a January 2009 Government Accountability Office (GAO) Report, which recommended 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." GAO-09-190 (January 2009). Congress directed FDA in the Safe Medical Devices Act of 1990, Pub. L. 101-629, to reexamine the preamendment devices and determine whether they should be down-classified, and to establish a schedule to promulgate regulations requiring PMAs for these Class III preamendment devices. However, as the GAO report found, the process still remains incomplete. FDA noted in its April 8, 2009 Press Release that the Agency has "made significant progress in reviewing and issuing new regulations" for all but 27 of the 149 Class III, pre-1976 types of medical devices that were identified in 1994 as not having yet been subject to FDA premarket approval. FDA has initiated the process for two device types, which will be subject to separate orders, and the remaining 25 device types are subject to the most recent order published in the Federal Register.

Outlook

It is unclear what impact the FDA's order may have on the marketing and availability of the affected devices, or other devices which rely upon them as predicates. Manufacturers of the 25 identified types of medical devices in the Agency's order, including an external heart

defibrillator, dialysis catheters, metal hip joints, spinal screws, intraocular eye lenses, and pacemaker devices, will have to submit the required information to the FDA by August 7, 2009. The information manufactures must submit is described in the Order and includes the device's indications for use, an explanation of how the device functions, device labeling, and a summary of all adverse safety and effectiveness information.

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