FDA NEWS RELEASE

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FDA issues draft guidance on device changes that warrant new premarket review

The U.S. Food and Drug Administration today issued draft guidance that clarifies when changes or modifications to a previously cleared 510(k) device require a new premarket submission.

The 510(k) process is the most common review path to market for lower-risk medical devices. To legally market a device, manufacturers must submit a premarket notification or 510(k) demonstrating that the new or modified product is substantially equivalent to another legally marketed medical device.

Manufacturers often make changes or modifications to a device after FDA clearance such as incorporating new technology or upgrading certain aspects of the device. Many changes do not require a 510(k) submission. But when the changes could significantly affect the product's safety or effectiveness or constitute a major change to the intended use of the device, another 510(k) must be submitted.

"We are making the regulatory process for medical devices less challenging by better describing our expectations," said Jeffrey Shuren, M.D., director of FDA's Center for Devices and Radiological Health. "In particular, manufacturers can continue to make innovative improvements to their devices and better plan for any updated submissions. This saves time and money."

The draft guidance clarifies the kinds of changes that trigger the need for a new submission, such as specific kinds of labeling changes, changes to the technology used in the device, changes in performance specifications, manufacturing changes, and changes in the materials used in the manufacture of the device.

This draft guidance is one of 25 action items listed in FDA's Plan of Action for Implementation of 510(k) and Science Recommendations launched in 2011 to enhance predictability, consistency, and transparency of the FDA's premarket review programs.

For more information:

510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change in an Existing Device, Draft Guidance

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm265274.htm

FDA: Medical Devices

http://www.fda.gov/MedicalDevices/default.htm

CDRH Plan of Action for 510(k) and Science

http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and

security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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