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FDA seeks comment on streamlined review of lower risk, new technology, devices
Reflects FDA's commitment to work with industry to bring safe and effective products to market quickly

The U.S. Food and Drug Administration today issued draft guidance for manufacturers that updates and streamlines the de novo review process used for certain innovative, low to moderate-risk medical devices that do not meet the requirements for clearance under the better-known 510(k) review process.

Before manufacturers may market most low to moderate-risk medical devices, such as certain catheters or diagnostic imaging devices, they must obtain FDA "clearance" of a premarket notification or 510(k), named after the section of federal law that describes this notification requirement. Generally, 510(k) submissions must demonstrate that the new device is substantially equivalent to another, legally marketed medical device that is also low to moderate-risk.

However, some low to moderate-risk medical devices are novel and not comparable to an already legally marketed device. Legislation passed by Congress in 1997 created the de novo process for these types of devices.

Currently, devices are only considered for the de novo program after the agency rejects a 510(k), establishing that the device is not substantially equivalent to another legally marketed device.

Although FDA has reviewed and granted a number of de novo petitions since the 1997 legislation, the program has been under-utilized because of process inefficiencies.

The draft guidance outlines a pathway for a concurrent 510(k) and de novo petition without duplicative data requirements, trimming up to 90 days from the process and fostering more efficient, early interaction between manufacturers and the FDA. It also provides clarity for manufacturers on the suitability of a device for the de novo process.

“Right now, the de novo process is cumbersome and requires extra work and effort from manufacturers and the agency,” said Jeffrey Shuren, M.D., director of the FDA’s Center for Devices and Radiological Health. “Creating a pathway for a concurrent 510(k) and de novo petition streamlines the de novo program, helping speed safe and effective devices to patients.”

This draft guidance is one of 25 action items listed in the FDA’s Plan of Action for Implementation of 510(k) and Science Recommendations launched earlier this year to improve the predictability, consistency and transparency of the agency’s pre-market review programs.

For more information:

Draft Guidance for Industry and Food and Drug Administration Staff: De Novo Classification Process (Evaluation of Automatic Class III Designation)
[2]

FDA: Medical Devices
[3]

CDRH Plan of Action for 510(k) and Science
[4]

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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