New FDA guidance on considerations used in device approval, de novo decisions

U.S. Food & Drug Administration

For Immediate Release: March 27, 2012
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New FDA guidance on considerations used in device approval, de novo decisions
Clinical data, risks, benefits and patient risk tolerance outlined in process

The U.S. Food and Drug Administration today published a first-of-a-kind guidance [2] for medical device manufacturers, describing how the benefits and risks of certain medical devices are considered during pre-market review.

Premarket approval (PMA) is the FDA process of scientific and regulatory review used to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury. The de novo process is available for low- and moderate-risk devices that have been found not substantially equivalent (NSE) to existing devices.

When evaluating PMA applications or de novo petitions, the FDA relies upon valid scientific evidence to assess safety and effectiveness. Both clinical and non-clinical data play a role in FDA's benefit-risk determinations.

The guidance includes a worksheet for device reviewers that incorporates the principal factors that influence benefit-risk determinations, such as the type, magnitude and duration of a risk or benefit, the probability that a patient will experience the risk, patient tolerance for risk, availability of alternative treatments, and the value the patient places on treatment.

The guidance:

- outlines the systematic approach FDA device reviewers take when making benefit-risk determinations during the premarket review process
- provides manufacturers a helpful tool that explains the various principal factors considered by the agency during the review of PMA applications, the regulatory pathway for high-risk medical devices, and de novo petitions, a regulatory pathway available for novel, low- to moderate-risk devices
- describes an approach that takes into account patients' tolerance for risks and perspectives on benefits, as well as the novelty of the device.

"This guidance clarifies this process for industry, which will provide manufacturers with greater predictability, consistency and transparency in FDA decision-making while allowing manufacturers and the FDA to use a common framework for benefit-risk determinations," said Jeffrey Shuren, M.D., director of FDA's Center for Devices and Radiological Health (CDRH).

The FDA will also increase the transparency of the decision-making processes by describing the worksheet analysis in the Summary of Safety and Effectiveness Data for PMAs and the decision summary review memos for de novo decisions.

"In addition to bringing clarity to our decision making for industry, this guidance will provide our reviewers with uniform and consistent guidelines to assess probable benefits and risks," said Shuren.

CDRH will train medical officers, review staff managers and device reviewers on the guidance to assure the guidance is applied consistently to submissions and petitions. CDRH reviewers will begin applying the guidance to incoming PMA and de novo submissions and to submissions already under review with decisions beginning on May 1.

The FDA is also developing external training modules to help industry and device sponsors understand how CRDH will apply the guidance.

For more information:
Medical Device Guidance Documents [3]

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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