FDA to Improve Most Common Review Path for Medical Devices

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SILVER SPRING, Md., Jan. 19, 2011 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration today unveiled a plan containing 25 actions it intends to implement during 2011 to improve the most common path to market for medical devices.

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Key actions include:

- Streamlining the "de novo" review process for certain innovative, lower-risk medical devices,
- Clarifying when clinical data should be submitted in a premarket submission, guidance that will increase the efficiency and transparency of the review process,
- Establishing a new Center Science Council of senior FDA experts to assure timely and consistent science-based decision making.

These actions will result in "a smarter medical device program that supports innovation, keeps jobs here at home, and brings important, safe, and effective technologies to patients quickly," said Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health (CDRH).

Before marketing most lower-risk medical products such as certain catheters or diagnostic imaging devices, manufacturers must provide the FDA with a premarket notification submission.

These submissions are known as 510(k)s for the section of the Federal Food, Drug, and Cosmetic Act that describes this notification requirement. Generally, 510(k)s must demonstrate that a proposed product is substantially equivalent to another, legally marketed medical device that is also lower-risk.

In September 2009, CDRH set up two internal working groups to address concerns relating to the premarket notification process -- industry argued that the 510(k) process was unpredictable, inconsistent and opaque, while consumers and health care professionals argued that the review process wasn't robust enough. At the same time
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