FDA Unveils 25 Initial 510(k) Changes, Refers Controversial Recommendations to the Institute of Medicine (IOM)

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On Wednesday the U.S. Food and Drug Administration (FDA) announced 25 changes to its process for approving medical devices under Section 510(k) of the Food, Drug, and Cosmetic Act. Section 510(k) is the 35-year-old system used to clear most devices for market. It allows lower-risk medical devices to be marketed, if they are substantially equivalent to devices already on the market.

The 510(k) system has been subject to increasing criticism in recent years, from critics who say it lets unsafe devices slip through, and industry groups that say the process is too opaque. The tide rose on these concerns last October, when FDA took the unprecedented step of acknowledging that a knee repair device cleared via 510(k) in 2008 should not have made it to market. As a result of these criticisms, FDA commissioned a report from the Institute of Medicine (IOM) on the workability of the 510(k) system and recommendations for improvement. FDA simultaneously tasked two internal working groups with reviewing the 510(k) process.

Wednesday’s announcement is the result of the internal groups’ findings – 55 initial recommendations for changes to the 510(k) program – further honed to implement 25 at this time, and refer more controversial and sweeping changes to IOM for deliberation in conjunction with their report. IOM’s results are due later this year.

Changes Implemented

1. FDA committed to create eight new Draft Guidances on the following, to be completed between June and December 2011.
   - 510(k) Modifications
   - Clinical Trials
   - De Novo Evaluation
   - Standards
   - Appeals
   - 510(k) Paradigm
   - Pre-Submission Interactions
   - Product Codes

2. FDA will make a number of "Internal and Administrative Matters" changes to improve the 510(k) process, to be completed between March and September 2011, including:
   - Creating a new internal Center Science Council, made up of senior agency experts, to oversee and audit the scientific/clinical aspects of the 510(k) program.
   - Developing a network of external experts who can help FDA address scientific issues in new medical technologies.

3. FDA will launch a series of "Programming and Regulatory" programs to fortify the 510(k) system, to be completed between March and December 2011, including:
   - Exploring use of an "assurance case" framework for submissions.
   - Analyzing use of multiple predicates.
   - Improving IDE process.
   - Implementing UDI system.
   - Improving third-party review system.

Recommendations Referred to IOM

1. Recission Authority – Clarify when FDA can fully or partially rescind 510(k) clearance.
2. Post Market Surveillance Authorities – Enhance FDA’s authority to require post market surveillance studies as a condition of 510(k) clearance.
3. Establishment of a Class IIb – Define a subset of devices requiring more data and evaluation to gain 510(k) clearance.
4. Predicate Clarification – Clarify when a device is no longer eligible to be used as a predicate.
5. Regulatory Terms Clarification and Consolidation – Consolidate the concepts “indication for use” and “intended use” into one definition.
6. **Device Review** – Require device companies to keep one exemplar device available for FDA's physical review upon request.

7. **Off-Label Use** – Gain express authority to consider an off-label use when determining intended use.

Early reaction to the announcement indicates that FDA has nimbly walked the fine line with which it is charged: encouraging innovation in the treatment and cure of disease while simultaneously protecting the public safety. Outgoing Medtronic Chief Executive Bill Hawkins predicted that the updates to 510(k) "will be neutral to slightly negative" for those trying to create new innovative medical devices, while Dr. Diana Zuckerman of the National Research Center for Women and Families said the FDA’s plan suggests "industry lobbyists won, and the public lost."

FDA itself, through Director of the Center for Devices and Radiological Health Dr. Jeffrey Shuren, said the changes announced Wednesday would 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. We look forward to implementing these changes in support of our overall mission: improving the health of the American public."