



September 30, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

RE: Docket No. FDA-2011-N-0556 [CDRH 510(k) Clearance Process; IOM Report: Request for Comments]

To Whom it May Concern,

On behalf of the Indiana Medical Device Manufacturers Council (IMDMC), I appreciate the opportunity to submit comments to the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) on the Institute of Medicine's (IOM's) report, "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years" (Docket No. FDA-2011-N-0556).

IMDMC is a trade association of medical device companies in Indiana. Our 51 member companies develop technologies that allow patients to lead longer, healthier, and more productive lives. The medical technology industry directly employs more than 20,000 of the state's residents, and is an important contributor to our economy.

The 510(k) process is an important component of FDA's premarket review and clearance of low- to moderate-risk medical devices. The 510(k) process is a key ingredient in medical progress and can be further strengthened to support innovation, while ensuring that patients have timely access to safe and effective technologies.

IMDMC supports FDA's position that the 510(k) program should not be eliminated. The 510(k) review process works well and has a strong safety record. The IOM committee itself acknowledges that there is no evidence that the 510(k) process is failing to assure safety and effectiveness. As FDA continues to move forward with its 510(k) implementation plan, IMDMC urges FDA to proceed with caution. Significant changes to the program could increase companies' regulatory burden and lead to patient delays in accessing safe and effective technologies.

However, IMDMC also believes that several of the proposed changes to the 510(k) process have merit and, if implemented, would result in a more predictable and consistent process that supports device innovation while continuing to ensure safety and efficacy. These include:

- Enhancing the training, professional development, and knowledge-sharing among reviewers and managers;
- Developing more definitive device-specific guidance documents that ensure consistency of device reviews;
- Simplifying and improving the "*de novo*" process for moderate-risk products that are too novel to meet the normal 510(k) "substantial equivalence" test but do not warrant review through the Premarket Approval (PMA) process;

Again, IMDMC appreciates the opportunity to comment on IOM's 510(k) report and commends FDA's continued commitment to an open, public dialogue on these issues. If you have questions about our comments or would like more information on the perspectives outlined here, feel free to contact me.

Respectfully,

Danelle Miller
IMDMC President

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