

July 27, 2010

**VIA ELECTRONIC DELIVERY**

Jeffrey E. Shuren, M.D., J.D.  
Director  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
WO66-5429  
Silver Spring, Maryland 20993

Dear Dr. Shuren:

As associations representing a broad range of innovators and entrepreneurial companies that comprise the many facets of the medical device industry, we are extremely interested in the Center for Devices and Radiological Health's (CDRH) work to modify the 510(k) process. As you know, improving the system by providing more certainty and transparency can speed life-saving products to patients. Adding unnecessary regulatory burdens, however, can conversely stifle new product development and drive manufacturers out of the U.S., thus negatively impacting patients as well as the economy.

We appreciate the town hall sessions and other outreach that you have conducted with a number of stakeholders. Consistent with this transparency and outreach effort before you propose changes to the 510(k) process, we believe it is essential that FDA allow an appropriate opportunity for the public to thoroughly evaluate and respond to any proposed reforms after the agency has made them public; and further, for the agency to carefully review and take into consideration these comments before implementing any changes to the 510(k) review process.

Specifically, we urge you to allow the public no less than 60 days to respond to the agency's proposed reforms. We also encourage the agency to take enough time (at least 60 days) to carefully consider public comments received before formulating its final rules and regulations. In order to allow the agency and stakeholders to prepare to implement such reforms, we also urge that implementation of any reforms begin not sooner than a length of time commensurate with the degree of change to current 510(k) regulations and quality management systems (QMS) processes. Finally, we urge the agency to develop a clear and consistent methodology for the implementation of any changes and to make all stakeholders aware of this methodology early in the process. Consistent with the above, we believe this methodology should provide all stakeholders with ample opportunity to become fully aware, understand and comment on the changes in policy.

We represent the many parts of the medical device industry and we share a common desire to diagnose and treat patients with the most innovative and highest quality devices in order to improve and save lives.

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We urge you to consult closely and broadly with each of our Associations, both collectively and independently, as you consider changes to the 510(k) review process. As we have done with the Institutes of Medicine (IOM), we pledge to make available to you our most informed experts and to provide objective information and data in as timely and responsive a manner as possible.

Furthermore, other stakeholders must be part of the process. We commit to facilitate for you connections to patients and experts in other sectors and industries world-wide. In so doing, we aspire to develop a constructive partnership with you that will serve your interests and the interests of the nation as you develop your recommendations.

Sincerely,

**Medical Device Manufacturers  
Association (MDMA)**  
Washington, DC

**Medical Imaging and Technology  
Alliance (MITA)**  
Arlington, VA

**California Healthcare Institute (CHI)**  
La Jolla, CA

**LifeScience Alley (LSA)**  
St. Louis Park, MN

cc: Margaret A. Hamburg, M.D.