

July 27, 2010

**VIA ELECTRONIC DELIVERY**

Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process  
Institute of Medicine  
Keck Center, W825  
500 Fifth Street, NW  
Washington, DC 20001

**Attention: Abigail Mitchell, Study Director and Senior Program Officer**

Dear Members of the Committee:

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 your ongoing efforts to assess the 510(k) system and in the recommendations you provide to modify the 510(k) process. Your efforts have the potential to change each part of the medical device industry in both positive and negative ways. Improving the system by providing more certainty and transparency can speed life-saving products to patients. Adding unnecessary regulatory burdens can conversely stifle new product development and thus negatively impact patients. For that reason, we feel it is essential that there be open lines of communication between the panel and all parts of the medical device industry and are committed to sharing with you information on all of our perspectives about our industry and its operations.

As we represent the many parts of the medical device industry, 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. However, different parts of the medical device industry, for very good reasons, implement this commitment in very different ways, in very different products, in the service of very different patients with very different health care needs. Consider that:

- Our companies range in size from very large multi-national corporations with interests around the world to very small entrepreneurs with just an idea.
- The products we manufacture range from the smallest implantable devices to capital equipment costing millions of dollars each and requiring entire rooms and suites to accommodate them.
- The products our companies manufacture take different paths to market. Some segments of the industry rely almost exclusively on the 510(k) process while others use a combination of PMAs and 510(k)s (and increasingly, are combination products that touch drugs or biologics).
- The medical device industry includes both diagnostic and therapeutic products and can work in tandem with drug or biologic combination products which, of course, serve different health care needs – some very specific and others quite broad and diffuse.
- The patients and the health needs that we address cover the spectrum of medical conditions, literally covering minor bruises and scratches to helping cure life-threatening cardiovascular, neurological, and oncological diseases.

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As you are aware, our products can only reach the public after they are cleared or approved by FDA. Your deliberations can provide key input to determine whether the clearance process is improved and streamlined, thereby providing patients with faster access to life-saving and life-improving products. Or, alternatively, risk making the process more burdensome, thus impacting innovation and ultimately reducing patient access to safe and effective products.

We believe this intrinsic variety, diversity, and differentiation among the products, companies, and patients must be acknowledged; that the IOM should broadly seek input from the full range of stakeholders involved; and that IOM should account for each of these differences in their recommendations.

We urge you to consult closely and broadly with each of our Associations, collectively and independently. 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 should 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,

**BayBio**

South San Francisco, CA

**BIOCOM**

San Diego, CA

**California Healthcare Institute (CHI)**

La Jolla, CA

**Florida Medical Manufacturers'**

**Consortium, Inc. (FMMC)**

St. Petersburg, FL

**The Health Industry Council**

Irving, Texas

**Indiana Medical Device Manufacturers'  
Council (IMDMC)**

Indianapolis, IN

**LifeScience Alley (LSA)**

St. Louis Park, MN

**Massachusetts Biotechnology Council**

Cambridge, MA

**Massachusetts Medical Device Industry  
Council (MassMEDIC)**

Boston, MA

**Medical Device Manufacturers  
Association (MDMA)**

Washington, DC

**Medical Imaging and Technology  
Alliance (MITA)**

Arlington, VA

**MedTech Association**

Syracuse, NY

**OCTANe**

Aliso Viejo, CA

**Pennsylvania Bio**

Wayne, PA

**Utah Technology Council**

Salt Lake City, UT