AL FRANKEN
MINNESOTA

SUITE
SH-320
202-224-5641

# United States Senate

WASHINGTON, DC 20510-2309

June 21, 2011

Dr. Jeffrey Shuren
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren:

I am writing to follow up on our meeting in May regarding your ongoing efforts to make the 510(k) process more transparent and efficient. I share your goals of ensuring consumer safety while encouraging the development of innovative new treatments for patients. I believe that these efforts are crucial to maintaining the role of the United States as the home to the best medical technology and treatment in the world.

While the FDA has made great strides in streamlining regulatory processes in recent years, inefficiencies in the 510(k) process continue to cause extraordinary delay in patient access to needed medical devices. These delays also create unsustainable burdens on medical manufacturers, many of whom are small businesses without the means to sustain themselves while waiting months or years for feedback from the FDA. The inefficiency of the process not only leads to unnecessary waiting times for patients before they receive needed treatment, but also creates a dangerous disincentive for the industry to participate in the medical device market in the United States.

I share your belief that patient safety must always be the first priority of the FDA, and I hope that this goal will spur a renewed willingness to look at current processes and make improvements where necessary. I understand that the FDA has asked the Institute of Medicine (IOM) to review the current 510(k) process and specifically to consider several issues relating to the device review and approval process. I believe that the medical device industry contains a wealth of expertise that is too often neglected when considering changes to the device review process. I strongly encourage you to establish a clear process for soliciting and considering the suggestions and concerns of the medical device industry on any and all recommendations made by the IOM before finalizing or implementing any changes to the process.

American companies are at the cutting edge of biomedical innovation, and I am proud that Minnesota continues to lead the way toward a future of unprecedented medical technologies that will no doubt revolutionize the way the world practices medicine. I hope to partner with the FDA, in collaboration with medical device manufacturers, in pursuit of this goal. I look forward to continuing to work with you toward the goal of reforming the 510(k) process to better protect patients and maintain the global leadership of the United States in biomedical technology innovation.

Sincerely,

Al Franken
United States Senator