Congress of the United States
Washington, DC 20515

September 6, 2012

Dr. Jeffrey Shuren
Director
Center for Devices and Radiological Health
Food and Drug Administration
White Oak Building 66
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren,

On behalf of the House of Representatives Medical Technology Caucus, we would like to thank you for working with us as we work to ensure that American patients have access to innovative and life-saving medical technologies. The recent Food and Drug Administration Safety and Innovation Act ("FDASIA") represents a delicate but hard-fought compromise to ensure this goal. Moreover, its overwhelmingly broad, bipartisan support indicates how critical it is to ensure patients do in fact have access to innovative treatments.

As you know, there are many provisions of FDASIA impacting medical devices that are already being implemented or will require implementation in the near future. As the Food and Drug Administration works to implement the device-related provisions of FDASIA, we ask that you meet with us on a quarterly basis to update the Agency's progress. These updates should include whether the Agency expects to meet required deadlines, whether the Agency expects to miss a required deadline, where the Agency stands in terms of implementing related regulations, and other information pertinent to ensuring that FDASIA provisions are executed on a timely basis.

We can all agree that FDASIA represents a historic milestone ensuring that American patients have access to safe and effective, life-saving medical treatments. The FDA plays a critical role in this, and we look forward to working with you as the law is implemented.

Sincerely,

Erik Paulsen
Member of Congress

Anna G. Eshoo
Member of Congress