May 24, 2018

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

Re: Docket No. FDA-2018-N-0235: Orthopaedic Sensing, Measuring, and Advanced Reporting Technology Devices; Public Workshop; Request for Comments

Dear Sir or Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, we are pleased to submit these comments in response to the Food and Drug Administration’s (FDA’s or Agency’s) request for comments on Orthopaedic Sensing, Measuring, and Advanced Reporting Technology Devices.

AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of such technology purchased annually around the world. These members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have less than $30 million in sales annually. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

General Comments

AdvaMed has general comments in response to FDA’s request for comments on Orthopaedic Sensing, Measuring and Advanced Reporting (SMART) Devices. We recommend that FDA establish a regulatory framework for orthopedic SMART devices that considers the risk and complexity of these devices. FDA should also allow companies to utilize the data collected from SMART devices to reduce pre-market data requirements, expand indications, and enhance post-market surveillance of these devices.
With respect to the regulatory framework, some possible examples of devices with different risk and complexity levels include:

- Products that are substantially equivalent to an existing device or fit within an approved device without changing the risk profile of the device.
- Products that include a detection technology that signals an action from the device (e.g., infection detection that informs drug delivery).
- Internal vs. external monitoring devices (e.g., technology in an implant vs. a sleeve that would monitor implant function from the exterior of the body).

At the April 30, 2018 public workshop, FDA mentioned it is considering taking outside certifications into account as part of demonstrating excellence. To ensure sponsors are working with appropriate certification systems to support or supplement the sponsor’s own verification and validation processes, FDA should publish a list of optional, acceptable outside certifiers such as Hi-Trust certification and Underwriters Laboratory (UL). FDA should also allow companies to establish self-certification.

Lastly, FDA should make clear that the recent initiatives related to cybersecurity of digital medical devices and the emphasis on Total Product Life Cycle (TPLC) apply to cybersecurity of SMART devices, specifically, the FDA’s Postmarket Management of Cybersecurity in Medical Devices Guidance and Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance.

Sincerely,

/s/

Tara Federici
Vice President
Technology and Regulatory Affairs