November 13, 2019

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2012-N-1021 for Center for Devices and Radiological Health Fiscal Year 2020 Proposed Guidance Development

Submitted electronically via www.regulations.gov

Dear Commissioner Sharpless:

The Heart Rhythm Society (HRS) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA or Agency) Center for Devices and Radiological Health (CDRH) proposed guidance development for fiscal year 2020 (FY20). Specifically, HRS would like to comment on (1) the inclusion of the development of a draft guidance document titled *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* as a Category A document; and (2) the necessity for an update of the 1990 document titled *Implantable Pacemaker Testing Guidance*.

HRS is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients as well as the primary information resource on heart rhythm disorders. Founded in 1979, HRS represents more than 6,500 specialists in cardiac pacing and electrophysiology, including physicians, allied professionals, scientists, and their support personnel. Cardiac electrophysiology is a distinct sub-specialty of cardiology. Most electrophysiologists are eligible for board certification in clinical cardiac electrophysiology and cardiology through the American Board of Internal Medicine. Cardiac electrophysiologists implant and manage patients with cardiac implantable electronic devices (CIEDs); perform electrophysiology studies to determine the mechanisms of rhythm disorders and perform curative catheter ablations to treat and prevent a variety of cardiac arrhythmias. The discipline of electrophysiology has undergone significant change in recent years, creating advances in the diagnosis and treatment of some of cardiology's most challenging diseases such as sudden cardiac death, atrial fibrillation, and heart failure. As these enhancements occur, HRS remains committed to improving the quality, safety, and efficiency of patient care.

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

The HRS supports the Agency's intent to prioritize and publish a revised draft guidance document in FY20. In February 2019, HRS, along with 44 other entities, provided comments to the docket (FDA-2018-D-3443) on draft guidance on the requirements for premarket submissions to reduce the risk of cybersecurity concerns with medical devices. HRS strongly encourages CDRH to address those comments in drafting the latest guidance document. HRS continues to offer expert support as the Agency considers further revisions.

Implantable Pacemaker Testing Guidance

The HRS strongly recommends that the Agency review and update the 1990 final guidance document titled *Implantable Pacemaker Testing Guidance*. This guideline describes a general framework for design verification testing of a safe and effective "bradycardia" pacemaker. On the FDA website, this guidance is marked as "content current as of March 27, 2018". Given nearly three decades of rapidly changing

technology and clinical research, the guidance is significantly outdated. Of note, the new guidance should align the requirements with subsequently published final guidance documents explaining the Agency's expectations for clinical trials. Please note that in 2004, the North American Society of Pacing and Electrophysiology (NASPE) became the Heart Rhythm Society (HRS). Please also note that HRS has no active protocols documenting this type of study, and so such reference should be removed. The new guidance should take into account advancements in the field such as remote monitoring and leadless cardiac pacemakers.

As the Agency considers revisiting this guidance document, HRS would like to be a partner and resource for clinical expertise. If you have questions regarding our comments or would like to discuss our initiatives or recommendations, please contact Laura Blum, Vice President, Health Policy at lblum@hrsonline.org.

Sincerely,

Andrea M. Russo, MD, FHRS
President