



August 30th, 2023

U.S. Food and Drug Administration  
Center for Devices and Radiologic Health  
Document Mail Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

**Attention:  
Increasing Patient Access to At-Home Use Medical Technologies  
FDA Docket 2023-N-1956**

To whom it may concern:

The Society of Interventional Radiology (SIR) is a professional medical association representing approximately 8,000 members, including most US physicians practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided procedural therapies, and applauds the Food and Drug Administration's efforts to support the development of the next generation of digitally enabled devices which may impact the practice of IR.

The emergence of "smart" medical devices, in which embedded digital technology confers legacy devices with greatly expanded capabilities, is of particular interest to the Society of Interventional Radiology. Short- and long-term implantable devices such as vascular access ports for blood sampling or medication infusion; percutaneous drainage catheters for the controlled evacuation of pathology fluid; blood pressure sensors for the monitoring of systemic, pulmonary, or portal hypertension; and pain management devices such as nerve stimulators are only a few examples in which data collected by the devices in the home setting can be digitally communicated to interventional health care teams for remote patient management. Such capabilities would substantially lessen the financial costs of frequent hospital visits for minor maintenance procedures and expand access to IR subspecialty expertise for patients who live in medically underserved regions.

The use of smart technologies has the potential to achieve the quadruple aim of healthcare: improving individual patient experiences, population health outcomes, and provider work satisfaction, all at reduced financial burden to the healthcare system.

The Society of Interventional Radiology urges the FDA to consider the substantial benefits to all stakeholders in the healthcare system when finalizing the regulatory guidance for the use of at-home medical devices.

Thank you for your commitment to patient safety and innovative healthcare solutions. We are committed to working closely with the FDA and look forward to collaborating with all stakeholders in facilitating the responsible development and regulation of at-home medical devices. If you require additional information, please contact Judi Buckalew, our Director of Government Affairs at [jbuckalew@sirweb.org](mailto:jbuckalew@sirweb.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'Alda L. Tam'. The signature is stylized with a large, sweeping initial 'A' and a sharp peak in the middle.

Alda L. Tam, MD, MBA, FSIR

President

Society of Interventional Radiology

Cc: Keith M. Hume, Executive Director

