



March 12, 2020

Food and Drug Administration
Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852
Submitted electronically: <http://www.regulations.gov>

Re: Docket No. FDA-2019-D-5422 – Draft Guidance for “Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters-Premarket Notification (510(k)) Submissions; Comments of the Society of Interventional Radiology.

Dear FDA Management Staff (HFA-305):

The Society of Interventional Radiology (SIR) is a professional medical society representing more than 8,000 members, including most US physicians who are practicing in the specialty of vascular and interventional radiology, and who frequently use PTA and Specialty Catheters. The Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapies. SIR appreciates the opportunity to comment on the Food and Drug Administration’s Draft Guidance for Peripheral Angioplasty (PTA) and Specialty Catheters- Premarket Notification (510(k)) submissions.

Over the past year, SIR has been working as part of the Paclitaxel Coalition in a multispecialty effort to address concerns over possible harm to patients being treated for symptomatic superficial femoral artery disease when revascularized using a drug (paclitaxel) coated balloon (DCB) or stents.

Our members have met several times with the FDA to clarify research findings and to advocate for our patient’s continued access to safe and effective therapies.

SIR recognizes that drug coated balloon catheters are outside the scope of this draft guidance. Because patient safety is our utmost priority, we urge the FDA to consider including language in the final guidance, explicitly distinguishing the regulatory pathway for DCBs and referencing the applicable consensus standards for drug coated balloons.

SIR appreciates the opportunity to provide comments on the proposed draft guidance. If additional information is required, please contact Sue Sedory, SIR Executive Director at ssedory@sirweb.org

Sincerely:

A handwritten signature in black ink that reads "Laura Findeiss". The signature is written in a cursive style with a large initial "L".

Laura Findeiss, MD, FSIR
President

Cc: Sue Sedory
Executive Director