

As of: 12/7/17 10:35 AM
Received: November 28, 2017
Status: Pending_Post
Tracking No. 1k1-9020-zr3g
Comments Due: January 08, 2018
Submission Type: Web

PUBLIC SUBMISSION

Docket: NRC-2017-0215
Yttrium-90 Microsphere Brachytherapy Sources and Devices Therasphere and SIR-Spheres

Comment On: NRC-2017-0215-0001
Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres;
Draft Guidance for Comment

Document: NRC-2017-0215-DRAFT-0071
Comment on FR Doc # 2017-24129

11/7/2017

82 FR 51655

Submitter Information

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Name: Jason Smith

General Comment

Dear Sir/Ma'am--

I am writing to express concern regarding changes to pathways to AU status. Having performed well over a 100 of these procedures, mostly in the last few years due to emerging excellent outcomes data and broad support with the hepatology world, I would hate to minimize the positive impact that this therapy will potentially have for many liver patients with hepatocellular carcinoma due to impediments to achieving AU status by otherwise qualified interventional radiologists. As a user of both Y-90 products, both from SirSpheres and TheraSpheres, there are definite advantages to having supervised and simulated in vitro case participation as part of education towards AU status. Proposed changes of eliminating pathway 2 towards becoming and AU will adversely impact availability of this valuable therapy from qualified interventionalists to their patients. Thank you kindly for your consideration of this matter. Sincerely, Jason Smith, MD. Chief Interventional Radiology, Loma Linda University Medical Center, Loma Linda, CA

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Template = ADM - 013
E-RIDS= ADM-03
Add= L. Dummerick (LD) 1