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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 Draft Guidance for Comment

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General Comment

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The proposed changes will significantly limit the ability of Interventional Radiology practitioners to meet the criteria to become authorized users for yttrium 90 microsphere therapy. This will result in a loss of access to this treatment for large numbers of patients. Moreover, the proposed changes appear to address a non-existent problem. The current system has served both practitioners and patients well without any discernible increase in adverse events.

Absent any firm evidence of harm to patients under the current system, there is no reason for the implementation of this rule change.

SUNSI Review Complete

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