

 JOHN T. VUCUREVICH
**REGIONAL
CANCER CARE INSTITUTE**

353 Fairmont Boulevard Rapid City, SD 57701 (605) 719-2300 FAX (605) 719-2310

2/22/18

United States Nuclear Radiation Commission Region IV

License Division

611 Ryan Plaza Dr.

Arlington, TX 76011

Subject: Continuation of amendment 103, license # 40-00238-04

Please find enclosed the required information concerning the completion of 3 proctored cases in the use of SIR-Speres Y-90 microspheres.

If there are any concerns please let me know,



James S. Mckee Jr.
Medical Physicist
Radiation Safety Officer
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Rapid City, SD 57701
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PUBLIC

- Immediate Release
 Normal Release

NON-PUBLIC

- A.3 Sensitive-Security Related
 A.7 Sensitive Internal
 Other: _____

Reviewer: 8102 Date: 2-28-18

602372



SIRTEX MEDICAL INC.
300 Unicorn Park Drive
Woburn, MA 01801
Tel: +1 (781) 721 3800
Fax: +1 (781) 721 3880

Ref: 105US03

February 21, 2018

Dr. Charles Voigt
Rapid City Regional Hospital
353 Fairmont Boulevard
Rapid City, SD 57701

Dear Dr. Voigt;

Re: SIR-Spheres Yttrium-90 Resin Microspheres Training, Evaluation, Certification (TEC) Program

I am writing to confirm that on February 7, 2018, Dr. Randall Smith presented and discussed the preparation of and procedures associated with SIR-Spheres yttrium-90 (Y-90) resin microspheres that are injected via the hepatic artery to treat patients with unresectable liver tumors. I am pleased to inform you that Sirtex considers that you and your staff are trained in the preparation and clinical aspects of treating patients with SIR-Spheres Y-90 resin microspheres.

This letter also certifies that you were proctored by a Sirtex certified proctor in the use of SIR-Spheres Y-90 resin microspheres on the following dates: January 10, 2018 (mapping); January 16, 2018 (dose administration); and February 7, 2018 (dose administration).

I would like to thank you and your team for your support and commitment to the Sirtex **Training, Evaluation, Certification (TEC)** Program.

Yours sincerely,

Shyam Srinivas, M.D., Ph.D.
Chief Medical Officer
Sirtex Medical, Inc.

cc: Barrett Olk, Regional Sales Manager
TEC@sirtex.com



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February 21, 2018

Dr. Charles Voigt
Rapid City Regional Hospital
353 Fairmont Boulevard
Rapid City, SD 57701

Dear Dr. Voigt;

Re: SIR-Spheres Yttrium-90 Resin Microspheres Authorized User (AU) Letter

This letter certifies that you completed three (3) patient cases under the supervision of and in the physical presence of a manufacturer representative in accordance with NRC's February 2016 Yttrium-90 Microsphere Brachytherapy Sources and Devices Licensing Guidance Training and Experience Section B Pathway 2 on January 16, 2018; February 7, 2018; and February 14, 2018.

Yours sincerely,

A handwritten signature in cursive script that reads "Shyam Srinivas, M.D., Ph.D.".

Shyam Srinivas, M.D., Ph.D.
Chief Medical Officer
Sirtex Medical, Inc.

cc: Barrett Olk, Regional Sales Manager