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
John T. Vucurevich Regional Cancer Care Institute
353 Fairmont Blvd
Rapid City, SD 57701
(605) 755-2339
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PUBLIC
☐ Immediate Release
☒ Normal Release

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

Reviewer: RJC 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

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 Yttirum-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,

Shyam Srinivas, M.D., Ph.D

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

cc: Barrett Olk, Regional Sales Manager