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SIRTEX MEDICAL INC.
300 Unicorn Park Drive
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March 23, 2017

Todd Everett, M.D.
Danbury Hospital
24 Hospital Ave
Danbury, CT 06810

06-08544-01
03001274

Dear Dr. Everett,

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 September 1, 2016; January, 19, 2017; and March 13, 2017.

Yours sincerely,

David N. Cade, M.D.
Chief Medical Officer
Sirtex Medical, Inc.

cc: George Cross, Regional Sales Manager
Ashley Cockerham, Professional Education Manager - Americas

394689



SIRTEX MEDICAL INC.
300 Unicorn Park Drive
Woburn, MA 01801
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Ref: 105US03

March 28, 2017

Todd Everett, M.D.
Danbury Hospital
24 Hospital Ave
Danbury, CT 06810

Dear Dr. Everett,

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

I am writing to confirm that on September 1, 2016, Dr. Rahul Patel 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. Dr. Patel also proctored you in the administration of SIR-Spheres Y-90 resin microspheres.

Given your prior experience administering SIR-Spheres Y-90 resin microspheres at Danbury Hospital under the supervision of Dr. Jeet Sandhu, I am pleased to inform you that Dr. Patel considers that you and your staff are trained in the preparation and clinical aspects of treating patients with SIR-Spheres Y-90 resin microspheres.

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

Yours sincerely,

A handwritten signature in black ink, appearing to read "David N. Cade".

David N. Cade, M.D.
Chief Medical Officer
Sirtex Medical, Inc.

cc: George Cross
Ashley Cockerham
TEC@sirtex.com



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Sharon Adams COO & Chief Nursing Officer Danbury Hospital 24 Hospital Avenue Danbury, Connecticut 06810	Date May 11, 2017
	License Number(s) 06-08544-01
	Mail Control Number(s) 594689
	Licensing and/or Technical Reviewer or Branch Medical Branch

This is to acknowledge receipt of your: Letter and/or Application Dated: March 23, 2017

The initial processing, which included an administrative review, has been performed. Notification
 Amendment Termination New License Renewal

There were no administrative omissions identified during our initial review.

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
 Follow the instructions on the form for submission.

The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
 U. S. Nuclear Regulatory Commission
 Division of Nuclear Materials Safety
 2100 Renaissance Boulevard, Suite 100
 King of Prussia, PA 19406-2713
 (610) 337-5260, (610) 337-5313,
 (610) 337-5398, (610) 337-5239