Sirtex Medical US Holdings, Inc.
Sirtex Medical Pty Ltd.
% Mr. Michael P. Hanley
Senior Regulatory Affairs Specialist
300 Unicorn Park, 2nd Floor
WOBURN MA 01801

October 23, 2020

Re: K202392
Trade/Device Name: SIR-Spheres Microspheres Activity Calculator (SMAC)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: August 19, 2020
Received: August 21, 2020

Dear Mr. Hanley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202392

Device Name
SIR-Spheres Microspheres Activity Calculator (SMAC)

Indications for Use *(Describe)*
The SIR-Spheres® Microspheres Activity Calculator (SMAC) is intended as a tool to assist with developing personalized dose activity calculations , based on relevant patient data, for patients undergoing selective internal radiation therapy (SIRT) with SIR-Spheres Y-90 resin microspheres . Using the BSA formula, the SMAC automatically performs calculations that are typically done manually by a physicist and/ or licensed healthcare practitioner. The algorithms used have been established and documented in scientific literature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5
510 (K) SUMMARY K202392

510(k) Summary – SIR-Spheres Microspheres Activity Calculator (SMAC)

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510 (k) summary has been provided in conformance with 21 CFR 807.92(c).

Date Prepared: August 19, 2020

A. Sponsor

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St Leonards NSW 2065, Australia

B. Contact

Michael Hanley
Senior Regulatory Affairs Specialist
781-721-3842
Email: Michael.Hanley@sirtex.com

C. Device Name

Trade Name:	SIR-Spheres Microspheres Activity Calculator (SMAC)
Common/Usual Name:	System, Imaging Processing, Radiological
Classification Panel:	Radiology
Pro Code:	KPS/Class II
Regulation Number	21 CFR 892.1200

D. Legally Marketed Device (Predicate Device)

The following legally marketed device has been used for comparison.

Proprietary/Trade Name
Trade Name: HERMES Hybrid3D v3.0 SIRT (**K181468**)

E. Description of the device that is subject of this premarket notification:

The SIR-Spheres Microspheres Activity Calculator (SMAC) is a software modelling program that is designed to assist physicians and licensed healthcare practitioners when prescribing Selective Internal Radiation Therapy (SIRT) with SIR-Spheres Y-90 resin microspheres. It allows physicians

and licensed healthcare practitioners to determine an individualized dose activity calculation based upon specific patient characteristics. The program computes the prescribed activity calculation using the Body Surface Area (BSA) formula that has been published in peer reviewed journals of medicine and models treatment parameters. This is a tool only and does not replace the need for the physician or licensed healthcare practitioner to make an independent determination of the therapy best suited for the patient.

The SIR-Spheres Microspheres Activity Calculator (SMAC) tool employs a simple algorithm to calculate Y90 dose activity based on the Body Surface Area (BSA) model and patient specific user inputs. The SMAC tool does not incorporate imaging capabilities.

The HERMES Hybrid3D SIRT (K181468) is an acceptable predicate device because both devices perform dosimetry calculations based on the BSA formula

$$\textbf{Calculated Activity (GBq)} = \left[\textbf{BSA} - 0.2 + \left\{\frac{\textbf{Tumor Volume}}{\textbf{Total Treatment Volume}}\right\}\right] \times \left[\frac{\textbf{Total Treatment Volume}}{\textbf{Total Liver Volume}}\right]$$

$$BSA\ (m^2) = 0.20247 \times height(m)^{0.725} \times weight(kg)^{0.425}$$

Figure 1: Prescribed activity calculation of SIR-Spheres resin microspheres

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F. Indications for Use/Intended Use

The proposed **SMAC Calculator** application has the following **Indications for Use:**

The SIR-Spheres® Microspheres Activity Calculator (SMAC) is intended as a tool to assist with developing personalized dose activity calculations, based on relevant patient data, for patients undergoing selective internal radiation therapy (SIRT) with SIR-Spheres Y-90 resin microspheres. Using the BSA formula, the SMAC automatically performs calculations that are typically done manually by a physician or licensed healthcare practitioner. The algorithms used have been established and documented in scientific literature.

The proposed SMAC Calculator application has the following Intended Use:

The SIR-Spheres Microspheres Activity Calculator (SMAC) is intended as a tool to assist with developing personalized dose activity calculations, based on relevant patient data, for patients undergoing selective internal radiation therapy (SIRT) with SIR-Spheres Y-90 resin microspheres.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed SMAC software is equivalent when compared to the marketed predicate in comparison to software design, function, and operation as the identified predicate. The table below provides the comparison of the devices.

Characteristic	Proposed Device: Sirtex SIR-Spheres Microspheres Activity Calculator (SMAC)	Predicate: Hermes Medical Solutions Hybrid 3D K181468	Comparison
Indications for Use	The SIR-Spheres® Microspheres Activity Calculator (SMAC) is intended as a tool to assist with developing personalized dose activity calculations, based on relevant patient data, for patients undergoing selective internal radiation therapy (SIRT) with SIR-Spheres Y-90 resin microspheres. Using the BSA formula, the SMAC automatically performs calculations that are typically done manually by a physician or licensed healthcare practitioner. The algorithms used have been established and documented in scientific literature.	Hybrid3D is a software application that can be used to process, display, analyze and manage nuclear medicine and other medical imaging data transferred from other workstations or acquisition stations	Similar Both software programs calculate dose based on the exact same SIRTEX BSA formula as seen in the instructions for use. Hybrid 3D includes more features than dose calculation, whereas the SMAC only provides the software automation of the formula.
Intended Users	Physicians and licensed healthcare practitioners	The user may be an experienced physician, medical physicist, technologist nurse or other operator who has been trained by an authorized distributor or	Very Similar

Characteristic	Proposed Device: Sirtex SIR-Spheres Microspheres Activity Calculator (SMAC)	Predicate: Hermes Medical Solutions Hybrid 3D K181468	Comparison
		by Hermes Medical Solutions.	
Device Environment	Hospital, Clinic Office Based Interventional Suite (OBIS)	Hospital Clinic	Similar: Both the proposed and predicate devices are intended to be used in licensed healthcare facilities
Operating Platform	The SMAC system is designed to be supported by the last two versions of the web browsers: Chrome, Firefox, Safari, Opera, Mobile Safari, and Internet Explorer (IE) mobile as well as Internet Explorer 9+ and android browser 2.3.	Microsoft Windows 7 & 10 (64 bit only) / Windows Server	Similar Proposed device's operating platform has been evaluated for browser compatibility.
Algorithms to Perform Calculations	Algorithm performs Y90 dose calculations based upon the Body Surface Area (BSA) model using patient specific characteristics.	Algorithm performs Y90 dose calculations based upon the Body Surface Area (BSA) model using patient specific characteristics.	Identical The proposed and predicate devices utilize the BSA Method to perform dose calculations.

H. Performance Data

The performance evaluation of the proposed SMAC Calculator included testing conducted in accordance to the following FDA Guidance Documents, domestic and international standards:

Results of this testing demonstrate safety and effectiveness of the proposed device and substantial equivalence.

I. Substantially Equivalent / Conclusion

The Proposed device is determined to be substantially equivalent to the predicate device based on:

- The Intended Use and Indications for Use
- Operating principles/technology
- Results of safety and performance testing
- Responses to questions posed in FDA 510 (k) "Substantial Equivalence" Decision Making Flowchart