December 6, 2018

Mirada Medical Ltd.
% Ms. Sarah Bond
VP Product Management
Oxford Center for Innovation, New Road
OXFORD, OX1 1BY OXFORDSHIRE
GREAT BRITAIN

Re: K182016
Trade/Device Name: Simplicit90Y
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 22, 2018
Received: October 25, 2018

Dear Ms. Bond:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182016

Device Name
Simplicit90Y

Indications for Use *(Describe)*
Simplicit90Y is a standalone software device that is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images.

Simplicit90Y supports the reading, rendering and display of a range of DICOM compliant imaging and related formats including but not limited to CT, PT, NM, SPECT, MR, SC, RTSS. Simplicit90Y enables the saving of sessions in a proprietary format as well as the export of formats including CSV and PDF files.

Simplicit90Y is indicated, as an accessory to TheraSphere®, to provide pre-treatment dosimetry planning support including Lung Shunt Fraction estimation (based on planar scintigraphy) and liver single-compartment MIRD schema dosimetry, in accordance with TheraSphere® labelling. Simplicit90Y provides tools to create, transform, and modify contours/Regions of Interest for calculation of Lung Shunt Fraction and Perfused Volume. Simplicit90Y includes features to aid in TheraSphere® dose vial selection, dose vial ordering and creation of customizable reports.

Simplicit90Y is indicated for post-treatment dosimetry and evaluation following Yttrium-90 (Y-90) microsphere treatment. Simplicit90Y provides tools to create, transform, and modify contours/Regions of Interest for the user to define objects in medical image volumes to support TheraSphere® post-Y-90 treatment calculation and evaluation. The objects include, but are not limited to, tumors and normal tissues, and liver volumes.

Simplicit90Y is indicated for registration, fusion display and review of medical images allowing medical professionals to incorporate images, such as CT, MRI, PET, CBCT and SPECT in TheraSphere® Yttrium-90 (Y-90) microspheres pre-treatment planning and post-Y-90 treatment evaluation.

For post-Yttrium-90 (Y-90) treatment, Simplicit90Y should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for the case where there is a need for retreatment using Y-90 microspheres.

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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510(k) Summary of Safety and Effectiveness

(The following information is in conformance with 21 CFR 807.92)

Date of summary:	21st July 2018
Submitter's name:	Mirada Medical Ltd
Submitter's address:	Oxford Centre for Innovation, New Road, Oxford. Oxfordshire, OX1 1BY United Kingdom
Submitter's contact:	Sarah Bond
Telephone number:	+44 (0)1865 261410

Device Proprietary Name:	Simplicit^{90}Y
Device Common Name(s):	Simplicit^{90}Y
Classification Name:	Class II: Picture Archiving and Communications System (892.2050) Product Code: LLZ

Predicate Device

510(k) Number	Trade Name	Manufacturer
K172218	MIM – Y90 Dosimetry	MIM Software Inc.

Reference Devices

510(k) Number	Trade Name	Manufacturer
K102687	Mirada RT	Mirada Medical Ltd.
K130393	Mirada RTx	Mirada Medical Ltd.
K101228	Mirada XD	Mirada Medical Ltd.

Intended Use

Simplicit^{90}Y is intended to be used by trained medical professionals for TheraSphere® pre-treatment dosimetry planning and post-treatment dosimetry evaluation following Y-90 treatment.

Simplicit^{90}Y is a medical image and information management system that is intended to receive, transmit, store, retrieve, display and process digital medical images, as well as create, display and print reports from those images. The medical modalities of these medical imaging systems include, but are not limited to, CT, MRI, SPECT and PET.

Simplicit^{90}Y provides the user with the means to display, register and fuse medical images from multiple modalities.

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Simplicit^{90}Y provides tools to create, transform, and modify contours for the user to define objects in medical image volumes for use in TheraSphere® pre-treatment dosimetry planning and for post-treatment dosimetry. The objects include, but are not limited to, tumors and normal tissues.

For post-Yttrium-90 (Y-90) treatment, Simplicit^{90}Y should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for the case where there is a need for retreatment using Y-90 microspheres.

Device Description

Simplicit^{90}Y is a software device which provides features and tools for use in pre-treatment dosimetry planning of TheraSphere® Y-90 microspheres treatment and post-treatment evaluation of Y-90 microspheres treatment and operates on Windows computer systems.

Simplicit^{90}Y pre-treatment dosimetry planning features include Lung Shunt Fraction estimation (based on planar scintigraphy) and liver single-compartment MIRD schema in accordance with TheraSphere® labelling. Simplicit^{90}Y additionally provides tools to support TheraSphere® dose vial selection, dose vial ordering and includes the creation of customizable reports.

After administration of Y-90 microspheres, Simplicit^{90}Y provides post-treatment dosimetry evaluation with multi-compartment and voxel-wise MIRD techniques applying the Local Deposition Model with scaling for known injected activity to assist the clinician in performing assessment of treatment efficacy and quality assurance, including assessment of absorbed dose to structures such as liver, lung and tumors.

Simplicit^{90}Y provides 2D and 3D image display and advanced dosimetry analysis tools including isodose contour line plan and dose volume histograms.

Simplicit^{90}Y provides tools for multi-modal image fusion using rigid and deformable registration capable of manual, semi-automated and fully automated operation. Simplicit90Y includes evaluation tools for assessment of registration quality.

Simplicit^{90}Y provides semi-automated and automated tools for segmentation of Region/Volume Of Interest on multi-modal images.

Simplicit^{90}Y supports the reading, rendering and display of a range of DICOM compliant imaging and related formats including but not limited to CT, PT, NM, SPECT, MR, SC, RTSS. Simplicit90Y enables the saving of sessions in a proprietary format as well as the export of RTSS, CSV and PDF files.

Simplicit^{90}Y should not be used to change a treatment plan after treatment has been delivered with Yttrium-90 (Y-90) microsphere implants.

Indications for Use

Simplicit^{90}Y is a standalone software device that is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images.

Simplicit^{90}Y supports the reading, rendering and display of a range of DICOM compliant imaging and related formats including but not limited to CT, PT, NM, SPECT, MR, SC, RTSS. Simplicit^{90}Y enables the saving of sessions in a proprietary format as well as the export of formats including CSV and PDF files.

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Simplicit^{90}Y is indicated, as an accessory to TheraSphere®, to provide pre-treatment dosimetry planning support including Lung Shunt Fraction estimation (based on planar scintigraphy) and liver single-compartment MIRD schema dosimetry, in accordance with TheraSphere® labelling. Simplicit^{90}Y provides tools to create, transform, and modify contours/Regions of Interest for calculation of Lung Shunt Fraction and Perfused Volume. Simplicit^{90}Y includes features to aid in TheraSphere® dose vial selection, dose vial ordering and creation of customizable reports.

Simplicit^{90}Y is indicated for post-treatment dosimetry and evaluation following Yttrium-90 (Y-90) microsphere treatment. Simplicit^{90}Y provides tools to create, transform, and modify contours/Regions of Interest for the user to define objects in medical image volumes to support TheraSphere® post-Y-90 treatment calculation and evaluation. The objects include, but are not limited to, tumors and normal tissues, and liver volumes.

Simplicit^{90}Y is indicated for registration, fusion display and review of medical images allowing medical professionals to incorporate images, such as CT, MRI, PET, CBCT and SPECT in TheraSphere® Yttrium-90 (Y-90) microspheres pre-treatment planning and post-Y-90 treatment evaluation.

For post-Yttrium-90 (Y-90) treatment, Simplicit^{90}Y should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for the case where there is a need for retreatment using Y-90 microspheres.

Substantial Equivalence

The proposed device was evaluated against the predicate device and found to be substantially equivalent on the basis that:

- The indications of the proposed device consist of a narrower scope than those of the predicate device.
- The technology of the proposed device is similar to the predicate device and the differences do not raise any new or different issues of safety and effectiveness.

Both devices provide similar tools with which to register and segment images for post-treatment dosimetry of Y-90 microspheres.

The key differences between the predicate device and the proposed device is that the proposed device is indicated for a narrower set of clinical applications than the predicate device as it is intended for Y-90 dosimetry only. The features and indications for the proposed device are substantially equivalent to the applicable features and indications of the predicate device.

Additionally, the proposed device is indicated for pre-treatment dosimetry for Y-90 as an accessory to TheraSphere®, where the predicate device is only intended for pre-treatment dosimetry for general purpose brachytherapy planning. Although the clinical context for pre-treatment dosimetry is different – the broad purpose of pre-treatment dosimetry is substantially the same.

The pre-treatment dosimetry features of the proposed device augment the use of TheraSphere® within the TheraSphere® labelling, perform in accordance with its intended use, and do not result in any new potential safety risks.

We conclude that the proposed device is substantially equivalent to the predicate device and performs as well as the applicable sub-set of the intended use of the predicate device and poses no unanswered questions with regard to safety and efficacy.

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Testing

Simplicit^{90}Y is validated and verified against its user needs and intended use by the successful execution of planned performance, functional and algorithmic testing included in this submission. The results of performance, functional and algorithmic testing demonstrate that Simplicit^{90}Y meets the user needs and requirements of the device, which are demonstrated to be substantially equivalent to those of the listed predicate device.

Verification and Validation for Simplicit^{90}Y has been carried out in compliance with the requirements of CFR 21 Part 820 and in adherence to the DICOM standard.

Conclusion

In conclusion, performance testing demonstrates that Simplicit^{90}Y is substantially equivalent to, and performs at least as safely and effectively as the listed predicate device. Simplicit^{90}Y meets requirements for safety and effectiveness and does not introduce any new potential safety risks.

