RADIATION PRODUCTS LLC
% Mr. Victor Pereira
Principal
VHP Consulting
7240 NW 63 Terrace
PARKLAND FL 33067

July 18, 2018

Re: K180027
Trade/Device Name: ACCUSYTE 3D Fiducial Marker
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 3, 2018
Received: June 13, 2018

Dear Mr. Pereira:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K 180027

Device Name
ACCUSYTE 3D Fiducial Marker

Indications for Use *(Describe)*

The ACCUSYTE 3D Fiducial Markers are used to mark the location of a tumor cavity after the tumor has been removed.

In addition, the Markers are indicated on situations where soft tissue needs to be marked for future medical procedure such as subsequent Radiation Therapy.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510 (k) Summary

This 510 (k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92.

Applicant: Surgical Radiation Products LLC

Date Prepared: April 29, 2018 (amended)

Contact Person: John D Corbitt MD
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Trade Name: ACCUSYTE™ 3D Fiducial Marker
Common Name: Implantable Radiographic Marker
Classification Name: Medical charged-particle radiation therapy system
Classification Number: 892.5050
Device Classification: Class II
Product Code: IYE
Predicate Device: CIVCO Suture-Type Marker (K071614)
Reference Devices: BioZorb Marker (K143484)
Foosin WEGO-PGLA Absorbable Suture (K130735)

Substantially Equivalent to:

The **ACCUSYTE™ 3D Fiducial Marker** is substantially equivalent in intended use, principle of operation, and technological characteristics to the CIVCO Suture-Type Marker (K071614), to the BioZorb Marker (K143484), and to the Foosin WEGO-PGLA Absorbable Suture (K130735).

Description of the Device subject to Premarket Notification:
The **ACCUSYTE™ 3D Fiducial Marker** is an implantable marker comprised of an absorbable suture (polylactic acid) component which absorbs completely in less than one year, and a permanent component, a Platinum or Gold Marker attached to the suture by a crimping operation similar to the operation use to attach the Stainless-Steel Needle.

The **ACCUSYTE™ 3D Fiducial Marker** is provided Sterile for single use and is implantable.

Indication for Use:

The **ACCUSYTE™ 3D Fiducial Markers** are used to mark the location of a tumor cavity after the tumor has been removed.

In addition, the Markers are indicated on situations where soft tissue needs to be marked for future medical procedure such as subsequent Radiation Therapy.

Technical Characteristics:

The **ACUSYTE™ 3D Fiducial Marker** has similar physical and technical characteristics to the predicative and reference devices, as illustrated in the table below:

Technical Characteristic	Subject Device	Primary Predicate	Reference Device	Reference Device
	ACCUSYTE™ 3D Fiducial Marker	**CIVCO Suture-Type Marker (K071614)**	**BioZorb Marker (K143484)**	**WEGO-PGLA Absorbable Suture (K130735)**
Overall Technological Characteristic	Radiographically visible permanent marker on an absorbable suture	Radiographically visible permanent marker on an absorbable suture	Radiographically visible permanent marker element in a bio-absorbable polymer space	Suture-N/A
Principle of Operation	Marker is secured on tumor cavity area for radiographic visualization of tumor site after removal	Marker is positioned into tissue site for radiographic visualization of tissue site	Marker is positioned into tissue site for radiographic visualization of tissue site	Suture holds marker in place during tissue healing process
Absorption time for suture and polymer	Less than 1 year (suture)	Unknown for suture	Longer than 1 year (Polymer)	Suture- Less than 1 year
Visualization Compatibility	ikV CT, 2D Linac- based kilovoltage and megavolt¬age X-ray imaging systems, and kV	X-Ray CT (presumed)	Mammography, Ultrasound, X-Ray, and CT	Suture-N/A

	cone-beam CT.			
Materials of Construction	Gold or Platinum/Iridium Marker component, absorbable suture (Glycolide-co-Lactide)	Gold Marker and absorbable suture	Titanium Markers and absorbable polymer (spacer)	Suture-Glycolide-co Lactide with Stainless Steel Needle
Overall Device Length	<0.5 cm (Marker)	<5cm (Marker)	2-5 cm (Marker)	Suture-45 cm
Typical Anatomic Treatment Site	Soft tissue tumor cavity site including breast	Breast	Soft tissue including breast	Suture- soft tissue
-Method of Marker Deployment	Surgically implanted	Surgically implanted	Manual, open surgical	Suture- surgical placement
Marker Stability	Sutured in place	Sutured in place	Tissue retention	Suture retains marker in place through healing process
How Provided	Sterile for single use	Sterile single use	Sterile single use	Suture-Sterile Single Use
Sterilization Method	ETO validated cycle with SAL of 10^{-6}	Unknown	Radiation	Suture- ETO validated cycle with SAL of 10^{-6}

Performance Data:

The Absorbable Suture component on the candidate device was tested as part of its 510 (k) submission (K130735) with the following tests:

- Bacterial Endotoxin (USP Pharmacopeia <85>) - Pyrogenicity
- Biocompatibility (ISO-10993) - suture component - Implant
- Physical Testing - USP 30 <861, <871, and <881 - suture component
- Residual Strength and Absorption Rate studies as outlined in FDA's Class II Special Controls Guidance Document: Surgical Sutures.

Performance data for the ACCUSYTE™ 3D Fiducial Marker device included:

- The Gold and Platinum/Iridium markers were bench tested for clarity of visualization using a phantom breasts model across computed tomography (CT), kilovoltage (kV), cone-beam CT (CBCT), and megavoltage (MV) linear accelerator imaging
- Radiographic Imaging 6-8 weeks after implantation
- Mammography imaging after 1-year post implantation

MRI Safety:

The ACCUSYTE™ 3 D Fiducial Markers are considered "MR Conditional"

Non-clinical testing has demonstrated the ACCUSYTE™3D Fiducial Marker device is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2- W/kg in the Normal Operating Mode
- Under the scan conditions defined above, the Accusyte™ 3D Fiducial marker is expected to produce a maximum temperature rise of ≤2℃ after 15-minutes of continuous scanning at 3 Tesla
- The image artifact caused by the Accusyte™ 3D Fiducial is not expected to extend more than 10-mm from this device when imaged with a gradient echo pulse sequence and a 3- Tesla MRI system.

The Accusyte™ 3D Fiducial and may be safely scanned with MRI under the conditions listed above. Scanning under different conditions may result in severe patient injury.

The **ACCUSYTE™ 3D Fiducial Marker** performance is equivalent to that of the predicate and reference devices in that it provides clear visualization of the tumor site, the candidate device secures the markers on soft tissue of the tumor cavity for a more accurate localization of the site, aiding in targeting the area for subsequent Radiation therapy and limiting exposure to adjacent tissue.

There were no complications reported from the candidate markers device during the human study, such as bleeding, pain, infection, inflammation, or tissue reactions. Therefore; demonstrating that the candidate device is safe and effective for its intended use.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation, and overall technological characteristics, the **ACCUSYTE™ 3D Fiducial Marker** is determined by Radiation Products LLC to be substantially equivalent to the existing legally marketed predicate device CIVCO Suture Type Marker.