DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2017

RadioMed Corporation
% Ms. Leah Easley
Quality and Regulatory Manager
3150 Stage Post Drive
Suite 110
BARTLETT TN 38133

Re: K161724
Trade/Device Name: Visicoil MR Marker (User Loaded), Visicoil MR Marker (Pre-Loaded)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 22, 2016
Received: June 22, 2016

Dear Ms. Easley:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For

Robert A. 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)*
K161724

Device Name
Visicoil MR Marker
Pre-Loaded Visicoil MR Marker

Indications for Use *(Describe)*

The Visicoil MR Marker and the Pre-Loaded Visicoil MR Marker are indicated for use to radiographically mark soft tissue for future therapeutic procedures.

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.

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1. Sponsor Name (Manufacturer)

RadioMed Corporation
3150 Stage Post Drive
Suite 110
Bartlett, Tennessee 38133
Telephone: (901) 432 7202 voice
(901) 432 7206 fax
Contact Individual: Leah Easley

Submission Dates:
K161724/S002 April 04, 2017
K161724/S001 Jan 18, 2017
K161724 May 26, 2016

2. Device Name

Proprietary Name:
- Visicoil MR Marker, Pre-Loaded Visicoil MR Marker

Common/Usual Name:
- Visicoil MR Marker, Pre-loaded Visicoil MR Marker

Classification Name:
- Medical charged-particle radiation therapy system (21 CFR 892.5050)

Device Class:
- II

Product Code:
- IYE

3. Identification of Predicate or Legally Marketed Device

The predicate devices for RadioMed™ Visicoil MR Marker are:

1. Pre-loaded Visicoil Marker (K070305)

Other Reference Devices:

2. Visicoil Marker (K031206)

4. Summary Device Description

Device Identification: the Visicoil MR is a helically wound coil of platinum wire. The product is available on a carrier for user-loaded implantation or pre-loaded in a needle.

Device Characteristics: The Visicoil MR is a linear fiducial marker. It is used for marking soft tissue for future therapeutic procedures.

Environment for Use: The Visicoil MR and Pre-Loaded Visicoil MR may be implanted in a healthcare facility, free standing clinic or physician's office.

Description of Device: The Visicoil MR Marker and the Pre-loaded Visicoil MR Marker is a sterile device, in the form of a platinum coil. Visicoil MR comes on a delivery

system, packaged in a Mylar/Tyvek pouch, sterilized by gamma sterilization. The Pre-Loaded Visicoil MR comes in a 18, 19, 20, 21, or 22g 304 stainless steel needle and stylet with a beeswax plug at the tip, packaged in a Mylar/Tyvek pouch sterilized by EO sterilization.

The coils ranges in length from 0.3cm to 2cm and have an outside diameter that ranges between 0.3mm and 1.0mm. Platinum has a dense mass which allows for imaging in all x-ray based imaging devices and other electro-magnetic properties help to enhance visibility within Magnetic Resonance Imaging (MRI).

The device is a passive device and is permanently implanted in the patient.

The Pre-loaded Visicoil MR will be manufactured, labeled, and packaged in accordance with the current FDA QSR and UDI regulation. To ensure compliance to specifications, upon completion of the manufacturing process and prior to release, the device will be inspected and tested in accordance with RadioMed standard operating procedures.

The product is not Electro Mechanical in nature so does not require EMC review.

Patient contacting materials: Visicoil MR and Pre-Loaded MR are comprised of Platinum and are permanently implanted. The Pre-Loaded Visicoil MR is loaded in a 304 stainless steel needle and stylet. The needle and stylet are for momentary patient contact for duration of procedure. The needle has a small amount of beeswax (Bone wax) at the tip to prevent the coil from falling out. A portion of the wax is permanently implanted into the body along with the coil as with the predicate device.

5. Intended Use

The intended use and indications for use of the modified device, as described in its labeling has not changed.

The Visicoil MR Marker and the Pre-Loaded Visicoil MR Marker are indicated for use to radiographically mark soft tissue for future therapeutic procedures.

6. Comparison of Technological Characteristics

The fundamental scientific technology of the modified device has not changed. The Visicoil MR Marker is manufactured from platinum (99.95%) as opposed to gold (99.95%). All other technology characteristics are identical.

Predicate Device: Pre-Loaded Visicoil Marker
510(k) Number: K070305

Other Reference Devices: Visicoil Marker
510(k) Number: K031206

7. Basis for Substantial Equivalence and Conclusion

The design of the Pre-Loaded Visicoil MR marker and the Visicoil MR marker is different from the predicate Pre-loaded Visicoil Marker and Visicoil products in the following ways:

The Visicoil MR Marker is manufactured from platinum as opposed to gold. All other characteristics are identical.

The design of the Pre-Loaded Visicoil MR marker and the Visicoil MR marker is similar to the predicate Pre-loaded Visicoil Marker and Visicoil products in the following ways:

The Visicoil MR indications for use are the same as the indications for use of the predicate device.

Biocompatibility testing per ISO 10993-1:2009 for the Visicoil MR has demonstrated biocompatibility for a permanent implant device that contacts tissue and bone.

Functional testing conducted to verify that the Visicoil MR is visible and stable and can be used safely under Magnetic Resonance Imaging (MRI) provides further demonstration that the Visicoil MR is safe and effective for its intended use.

Conclusion

The change in material composition does not adversely affect the safety or effectiveness of the new device. The new markers are functionally equivalent to the predicate device, with the additional characteristic of now being that they are highly visible when using MRI.