Section J

510k Summary

1. Sponsor Name

RadioMed Corporation
3150 Stage Post Drive
Bartlett, Tennessee 38133
Telephone: (978) 807 1017 voice
(901) 432 7206 fax
Contact Individual: Gordon Roberts

2. Device Name

Proprietary Name: RadioMed™ Pre Loaded CK Visicoil Marker
Common/Usual Name: RadioMed™ Pre Loaded CK Visicoil Marker
Classification Name: System X-Ray, Tomography, Computed

3. Identification of Predicate or Legally Marketed Device

The predicate devices for RadioMed™ Soft Tissue Marker are:

1. Visicoil™ Pre Loaded Visicoil Marker (K070305)
2. Brachy Needles/Spacer/Sleeve/Marker (K103449)

4. Device Description

The Pre-Loaded CK Visicoil a sterile device, in the form of two gold coils and a PGLA spacer loaded into a 17, 18 or 19g needle. The coil ranges in OD between 0.35mm and 1.2mm.

The Pre-Loaded CK Visicoil is packaged sterile, for single use. Sterilization is achieved by a validated EO sterilization method.

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

Depending on the coil size (0.35mm, 0.50mm, 0.75mm, or 1.2mm), the Pre-Loaded Visicoil Marker will be delivered using either a 17, 18 or 19 gauge needle. The coils and spacer are supplied loaded and ready for use in the applicable needle.

5. Intended Use

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

The Pre-Loaded CK Visicoil is 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.

Predicate Device: Pre Loaded Visicoil Marker

510(k) Number: K 070305

Predicate Device: Brachy Needles/Sleeves/Spacers/Markers

510(k) Number: K103449

The design of the predicate Visicoil CK Marker is identical to the Pre-Loaded Marker as it is a gold metallic coil, ranging from 0.5cm-3cm in length. However, 2 coils will be loaded into a needle and separated by a spacer. This configuration is identical to the second predicate product (K103449)

7. Performance Testing

Summary of standards achieved:

ISO 10993 Biological Evaluation of Medical Devices
FDA QSR 21 CFR Part 820 Good Manufacturing Practices

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Gordon Roberts
Director, QA/RA
RadioMed Corporation
3150 Stage Post Drive
BARTLETT TN 38133

APR 19 2012

Re: K120859
Trade/Device Name: Pre-Loaded CK Visicoil Gold Marker
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: March 20, 2012
Received: March 22, 2012

Dear Mr. Roberts:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

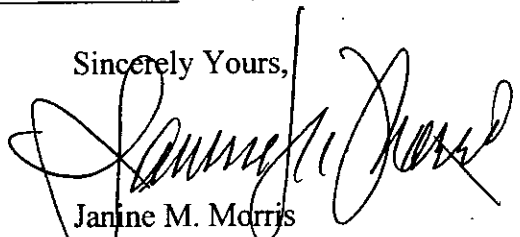
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use
510(k) Number (if known): K120859

Device Name: Pre-Loaded CK Visicoil Gold Marker

Indications For Use: Pre-Loaded CK Visicoil Gold Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120859

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)