K031206

Section J

510k Summary

1. Sponsor Name

RadioMed Corporation
One Industrial Way
Tyngsboro, Massachusetts 01879-1400
Telephone: (978) 649-0300 voice
(978) 649-0333 fax
Contact Individual: Gordon Roberts

2. Device Name

Proprietary Name: RadioMed™ Soft Tissue Marker
Common/Usual Name: RadioMed™ Soft Tissue 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. The RadioMed™ Marker, K022326
2. The Implanter/Adjustable/Anderson's Marker, K940121
3. The Extracranial Marker (K number unknown)

4. Device Description

The RadioMed™ Soft Tissue Marker is a non-sterile device, in the form of a gold coil that ranges in OD between 0.75mm and 1.2mm.

The RadioMed™ Soft Tissue Marker is packaged non-sterile, single use, and is to be sterilized by the end user in accordance with a validated sterilization process. Sterilization is achieved by exposure to steam autoclave.

The RadioMed™ Soft Tissue Marker 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.

The RadioMed™ Soft Tissue Marker will be delivered using either a 17 gauge or 18 gauge needle and stylet.

K031206

5. Intended Use

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

RadioMed™ Soft Tissue Marker 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: RadioMed™ Marker

510(k) Number: K022326

The design of the predicate RadioMed Marker is identical to the RadioMed Soft Tissue Marker except for the outside diameter dimension and material from which it is manufactured.

It is a metallic coil, ranging from one centimeter to six centimeters in length.

Predicate Device: Anderson Marker

510(k) Number: K940121

Predicate Device: Extracranial Marker

510(k) Number: Not Known

The material of the predicate Anderson Marker (K940121) and the Extracranial Marker is metallic gold, which is identical to the material used in the manufacture of the RadioMed™ Soft Tissue Marker.

In addition to the predicates referenced in this document, metallic gold is widely used in a number of other applications including dental restorative materials, surgical devices (ref. Microvasive Gold Probe; K970278), and other implants such as (Embogold Microsphere K010026, Boston Scientific, NiRoyale Elite Premounted Stent System (P980001/S07) and (Meddev contour design gold eyelid implant K011740).

Because the patient-contacting material used in the proposed RadioMed™ Soft Tissue Marker is known to have a safe history of use in currently marketed

K031206

medical devices, no additional biocompatibility testing has been performed in support of this Premarket Notification.

7. Performance Testing

Summary of standards achieved:

FDA QSR 21 CFR Part 820 Good Manufacturing Practices
AAMI Standard 11134-1994 Recommended practice for Steam Autoclave Visibility Studies (see section H – Performance Testing)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Mr. Gordon Roberts
Director, Quality Assurance
and Regulatory Affairs
RadioMed Corporation
One Industrial Way
TYNGSBORO MA 01879

Re: K031206
Trade/Device Name: RadioMed™ Soft Tissue Marker
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: April 15, 2003
Received: April 16, 2003

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 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K031206

Section E

Indications For Use

RadioMed™ Soft Tissue Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031206