K022326

Appendix 5
510(k) Summary

JAN 31 2003

1. Sponsor Name

RadioMed Corporation
One Industrial Way,
Tyngsboro, Massachusetts 01879
Telephone: (978) 649 0300
Fax: (978) 649 0333
Contact Person: Gordon Roberts

2. Device Name

Proprietary Name: RadioMed™ Marker
Common/Usual Name: RadioMed™ Marker
Classification Name: Implantable Marker

3. Identification of Predicate of Legally Marketed Device

The predicate devices for the RadioMed™ Marker are:
United States Surgical Auto Suture Site Marker Staple, K983400
Senorx Gel Mark™ Biopsy Site Marker, K000060
Genetra™ Source, K013660

4. Device Description

The RadioMed™ Marker is a non-sterile, disposable device in the form of a rhodium coil that is 0.35mm in diameter.

5. Intended Use

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

6. Comparison of Technological Characteristics

The design of each of the predicates and the RadioMed™ Marker is a metallic wire or coil that is visible as a marker under fluoroscopy or ultrasound. The material used in the RadioMed™ Marker is rhodium, which is identical to the Genetra ™ Source and passes biocompatibility testing per ISO 10993-1, and as shown in the animal and bench studies, is visible under fluoroscopy, ultrasound, CT and x-ray.

7. Performance Testing

Summary of Standards Achieved:
FDA QSR 21 CFR Part 820 Good Manufacturing Practices
ISO 10993-1 1992 (E) Biological Evaluation of Medical Devices
AAMI Standard 11134-1994 Recommended Practice for Steam Autoclave
Visibility Testing (see section V)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2003

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

Re: K022326
Trade/Device Name: RadioMed™ Marker
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 JAK and IYE
Dated: October 24, 2002
Received: November 4, 2002

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

510(k) Number (if known): K022326

Device Name: RadioMed™ Marker

Indications For Use: RadioMed™ Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022326