RIVERPOINT
MEDICAL

510(k) Summary

K103449

FEB 25 2011

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
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Registration Number:	3006981798
Contact Person:	Douglas Rowley (503) 517-8001
Date of Preparation:	November 12th, 2010

510(k) Type

Abbreviated

Device Names

Trade Names:	1. Brachytherapy Needles 2. RP Sleeve 3. RP Spacer 4. Gold Marker
Common Names:	Brachytherapy Needle Accessory to Sleeve Spacer Gold Marker
Classification Names:	Brachytherapy Needles, Sleeves, Spacers: System, applicator, radionuclide, manual and Source, Brachytherapy, radionuclide (or accessory to); Gold Markers: Medical Charged Particle Radiation Therapy System

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Device Classification

FDA Class: 2 (all)

Product Classification:

1. Brachy Needles: 892.5730 Radionuclide Brachytherapy Source
2. Sleeves: 892.5730 Radionuclide Brachytherapy Source
3. Spacers: 892.5730 Radionuclide Brachytherapy Source
4. Gold Markers: 892.5050 Medical Charged Particle Radiation Therapy Sytem

Product Codes:

1. Brachy Needles: KXK
2. Sleeves: KXK
3. Spacers: KXK
4. Gold Markers: IYE

Predicate Devices (applicable 510(k) number listed):

1. RP Brachytherapy Needles: CP Medical, K071550
2. RP Sleeve: CP Medical, K034062
3. RP Spacer: CP Medical, K010621
4. Gold Marker: Cortex Manufacturing, K100267

Special Controls

FDA Guidance "Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources" was followed (as applicable) during the preparation of this submission due to the product classifications selected for these items.

Device Descriptions

Riverpoint Medical Brachytherapy Needles and accessories are devices which are used together or independent of each other during Brachytherapy or other IMRT procedures. Intended uses and material information is included below.

Brachytherapy Needles are used to deliver a separately obtained radionuclide source and/or accessory into the patient at the desired location. Intended uses and material information is included below.

RP Sleeves are composed of an extruded polymer or copolymer material with known biocompatibility which can be used with or without RP Spacers to facilitate the placement of radionuclide seeds into the patient during Brachytherapy or IMRT procedures.

Gold Markers consist of ≥99.99% which can be implanted in order to provide increased visibility at the location of implant. Markers are to be available in a variety of sizes and configurations as desired by customers.

All devices within this submission are provided sterile for one-time use or non-sterile for further processing, and are sterilized via Ethylene Oxide when applicable.

Intended Uses

Brachytherapy Needles:

RP Brachytherapy Needles are intended to be used for the placement of radionuclide seeds, and/or gold markers and/or Brachytherapy spacer/sleeve accessories during Brachytherapy or IMRT procedures.

Sleeves:

The RP Sleeve is intended to be used to facilitate the placement and containment of radioactive seeds and gold markers with or without spacers into the body during Brachytherapy or IMRT procedures.

Spacers:

The RP Spacer is intended to be used during Brachytherapy or IMRT procedures to facilitate the implant of radionuclide seeds or gold markers at predetermined intervals within the body tissue. Spacers are indicated for use in soft tissues or organ tissue, but not to be used during cardiovascular or neurological procedures.

Gold Markers

RP Gold Markers are intended to provide localization information during Brachytherapy, IMRT, or other procedures involving radiation treatments.

Safety and Effectiveness

Riverpoint Medical Brachytherapy Needles and associated accessories have been designed and manufactured to be substantially equivalent to the predicate devices listed in this submission for all aspects of safety and effectiveness. Although the majority of the product classifications selected for the devices within this submission list radionuclide sources, none of the devices within this submission contain any amount of radioactive material.

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. Doug Rowley
RA/QA Manager
Riverpoint Medical
825 NE 25th Ave
PORTLAND OR 97232

FEB 25 2011

Re: K103449
Trade/Device Name: Brachytherapy Needle, Brachytherapy Sleeve, Brachytherapy Spacer, and Gold Markers
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: November 19, 2010
Received: November 23, 2010

Dear Mr. Rowley:

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,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

RIVERPOINT
MEDICAL

Indications for Use Statement

510(k) Number: Unknown at this time K103449

Device Name: Brachytherapy Needle

Trade Name: Brachytherapy Needle

Indications for Use:

RP Brachytherapy Needles are intended to be used for the placement of radionuclide seeds, and/or gold markers and/or Brachytherapy spacer/sleeve accessories during Brachytherapy or IMRT procedures.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

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

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Indications for Use Statement

510(k) Number: Unknown at this time K103449

Device Name: Brachytherapy Sleeve

Trade Name: RP Sleeve

Indications for Use:

The RP Sleeve is intended to be used to facilitate the placement and containment of radioactive seeds and gold markers with or without spacers into the body during Brachytherapy or IMRT procedures.

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

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

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Office of In Vitro Diagnostic Device Evaluation and Safety

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Indications for Use Statement

510(k) Number: Unknown at this time K103449

Device Name: **Brachytherapy Spacer**

Trade Name: **RP Spacer**

Indications for Use:

The RP Spacer is intended to be used during Brachytherapy or IMRT procedures to facilitate the implant of radionuclide seeds or gold markers at predetermined intervals within the body tissue. Spacers are indicated for use in soft tissues or organ tissue, but not to be used during cardiovascular or neurological procedures.

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

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Indications for Use Statement

510(k) Number: Unknown at this time K103449

Device Name: Gold Markers

Trade Name: Gold Markers

Indications for Use:

RP Gold Markers are intended to provide localization information during Brachytherapy, IMRT, or other procedures involving radiation treatments.

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

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