K034062

JAN 3 0 2004

Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the proposed CP Medical CP-SLEEVE component device, Special 510(k).

Manufacturer:

CP Medical, Inc.
2414 NE Pacific Avenue
Portland, OR 97232
PHONE: (503) 232-1555
FAX: (503) 230-9993

Contact Person:

Mary Ann Greenawalt, VP
Legal & Regulatory Affairs

Device Name:

Trade Name: Brachytherapy Sleeve Accessory

Common Name: Accessory to seed and spacer components and radionuclide brachytherapy Source device

Proprietary name: Carrier Sleeve

Classification: System, applicator, radionuclide, manual & Source, brachytherapy, radionuclide (accessory to)

Date Prepared: December 15, 2003

Predicate Device: The predicate device to the CP Medical CARRIER SLEEVE accessory device is the CP Medical, K013975, Placement Sleeve for Brachytherapy Procedures and the RIVER Medical Absorbable Seeding PDO Spacer component (K021311)

Device Description: The CP Medical CARRIER SLEEVE consists of synthetic absorbable polymer or copolymer material, braided and non-braided, which is used with absorbable seeding spacers to facilitate the introduction of radionuclide seeds and spacers into the body during Brachytherapy procedures.

Intended Use: CP Medical's synthetic, absorbable placement sleeve accessory is intended to be used with absorbable seeding spacers to facilitate the introduction of radionuclide seeds and spacers into the body during Brachytherapy procedures. It is used to orient, hold, carry and maintain spacing of the radionuclide seeds and the spacer component.

Indications: The CP Medical CARRIER SLEEVE component device is indicated for use as a accessory in brachytherapy procedures. It is supplied non-sterile or sterile as a single-use device. The CP-Sleeve is indicated for use in soft tissue or organ tissue but should not be used during cardiovascular or neurological procedures.

Comparison of Technological Characteristics: The proposed device, the CP Medical CARRIER SLEEVE is comprised of a synthetic absorbable material and is intended to facilitate the loading, delivery and implantation of radioactive seeds and spacers. Similarly, the predicate devices are composed of synthetic absorbable material intended to facilitate the loading, delivery and implantation of radioactive seeds and spacers.

end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2004

Ms. Mary Ann Greenawalt
VP Legal & Regulatory Affairs
CP Medical, Inc.
RIVER Medical (O/O # 9052608)
836 NE 24th Avenue
PORTLAND OR 97208

Re: K034062
Trade/Device Name: Carrier-Sleeve Synthetic Absorbable Braided and Non-Braided Placement Sleeve
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: December 30, 2003
Received: January 5, 2004

Dear Ms. Greenawalt:

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 such 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: K034062

Device Name(s): Carrier-Sleeve

Intended Use(s) of the Device:

CP Medical's synthetic, absorbable placement sleeve accessory is intended to be used with absorbable seeding spacers to facilitate the introduction of radionuclide seeds and spacers into the body during Brachytherapy procedures. It is used to orient, hold, carry and maintain spacing of the radionuclide seeds and the spacer component.

The Carrier Sleeve is indicated for use in soft tissues or organ tissue but should not be used during cardiovascular or neurological procedures.

Please do not write below this line - continue on another page if necessary

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Clegerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K034062

Prescription Use ✓ or Over-The-Counter Use _____

(per 21 CFR 801.109)