SEP 17 2004 K041894 1/1

Summary

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 CP Medical absorbable seeding spacer product.

Manufacturer: CP Medical, Inc.
803 NE 25th 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:	Polyblend surgical suture
Common Name:	Nonabsorbable polyblend surgical suture
Proprietary name:	CP Fiber
Classification:	Class II; GAT

Date Prepared: July 8, 2004

Predicate Device: The predicate device to the proposed CP Medical polyblend surgical suture, CP Fiber, is the existing CP Medical polyester surgical suture device, K001172 and Arthrex's FiberWIRE™ polyblend suture K010673, K021434.

Both predicate and proposed devices are indicated for use in soft tissue approximation; both meet USP for nonabsorbable sutures, may be silicone-coated or uncoated, and may be dyed or undyed with an appropriate FDA listed color additive. The sutures may also be provided with or without a standard needle attached.

Device Description:

The polyblend surgical suture meets USP requirements as described in the USP monograph for nonabsorbable surgical sutures.

CP Medical non-absorbable polyblend surgical sutures made with a braided, twisted core of polyethylene terephthalate and a polyethylene cover, are available in sterile form to an SAL of 10^{-6}. Sterilization is performed by either Ethylene Oxide or Gamma Irradiation.

Indications for Use:
General soft tissue approximation including use in cardiovascular, ophthalmic, and neurological procedures.
end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2004

Ms. Mary Ann Greenawalt
Vice President Legal & Regulatory
CP Medical
803 NE 25th Avenue
Portland, Oregon 97232

Re: K041894
Trade/Device Name: CP Fiber, Non-Absorbable Polyblend Surgical Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable PET surgical suture
Regulatory Class: II
Product Code: GAT
Dated: August 10, 2004
Received: August 18, 2004

Dear Ms. Greenwalt:

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 (301) 594-4659. 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 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041894

Device Name: CP Fiber, Non-Absorbable Polyblend Surgical Suture

Indications for Use:

General soft tissue approximation including use in cardiovascular, ophthalmic and neurological procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041894

Prescription Use X or Over the Counter Use ____

(per 21 CFR 801.109)