K030786

MAY 0 6 2003

SAFETY AND EFFECTIVENESS 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 Volume 21 of the Code of Federal Regulations, this is to serve as a Summary of Safety and Effectiveness for the proposed CP Medical synthetic absorbable monofilament surgical suture.

Manufacturer: CP Medical, Inc.
836 NE 24th Avenue
Portland, OR 97232
Phone: 503-232-1555
FAX: 503-230-9993

Contact Person: Mary Ann Greenawalt, VP Legal & Regulatory Affairs

Device Name: MonoSwift™ - synthetic absorbable monofilament suture
Classification: Class II

Date Prepared: March 5, 2003

Device Description: The proposed device is a synthetic absorbable monofilament surgical suture comprised of polydioxanone, trimethylene-carbonate and caprolactone copolymers. These polymers, individually, and as co-formulated herein, are substantially equivalent to other synthetic absorbable monofilament sutures in commercial distribution today.

Predicate Devices: The proposed device is substantially equivalent to CP Medical's polydioxanone surgical suture and is similar in absorption rates to CP Medical's collagen suture material.

Indications: MonoSwift™ is indicated for use in soft tissue approximation and/or ligation but not for use in cardiovascular or neurological surgery, microsurgery or ophthalmic surgery.

Intended Use: MonoSwift™ is intended to be used for surgical wound closure.

Summary of Clinical and Non-Clinical Studies:
Meets recognized consensus standards for surgical suture, United States Pharmacopoeia and ISO 10993 biocompatibility.

Comparison of Technological Characteristics:
The device has similar characteristics (chemistry, material and composition) as the predicate devices. Manufacture of this device, including QC testing, is in substantial compliance with current QSR and ISO quality standards.

end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary Ann Greenawalt
Vice President, Legal and
Regulatory Affairs
CP Medical, Inc.
836 NE 24th Avenue
Portland, Oregon 97232

MAY 0 6 2003

Re: K030786
Trade/Device Name: Monofilament-Synthetic Absorbable Monofilament Surgical Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: II
Product Code: NEW
Dated: March 10, 2003
Received: March 12, 2003

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 (301) 594-4659. 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,

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

INDICATIONS FOR USE

510(k) (if known): K934786

DEVICE Name: Monofilament -Synthetic Absorbable Monofilament Surgical Suture

Indications for Use:

CP Medical's synthetic absorbable monofilament is indicated for use in soft tissue approximation and/or ligation but not for use in cardiovascular or neurological surgery, microsurgery or ophthalmic surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____

(Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K030786