CP Medical
Portland, Oregon

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K013274

510(K) SUMMARY

NOV 16 2001

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990. 21 CFR 807.92

Device Name:

Trade Name: Mono-Dox, Synthetic Absorbable Suture, Sterile

Common Name(s): Suture Synthetic Absorbable Surgical, Polydioxanone

Classification Name(s): Suture, Absorbable, Synthetic, Polyglycolic Acid

Establishment Name, Contact & Registration Number:

Name: C.P. Medical, Inc.
836 N.E. 24th. Ave
Portland, Oregon 97232
Tele: (503) 232-1555
Fax: (503) 230-9993
FDA REG.No. 3032563

Contact: Mary Ann Greenawalt (Director of Regulatory)

Classification:

Device Class: Class II
Classification Panel: General & Plastic Surgery
Product Code: GAM

Intended Use:

Mono-Dox, Monofilament Absorbable Synthetic Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. *Mono-Dox* is not indicated for use in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are useful where an absorbable suture with extended wound support (up to six weeks) is desirable.

Equivalent Predicated Device:

C.P. Medical believes that the *Mono-Dox*, Absorbable Synthetic (Polydioxanone) Suture is substantially equivalent to the following absorbable suture marketed by Ethicon, Inc.:

PDS II, Synthetic Absorbable Polydioxanone Surgical Sutures

With respect to substantial equivalence, the comparison device represents a virtually identical device. Materials, packaging, sterilization methods, sizes multi- and monofilament, dyed and undyed as well as functional characteristics (absorption rate, strength, etc.). Equivalency can also be drawn with respect to the design, material composition, performance and intended use. *Mono-Dox* and PDS II sutures both meet or exceed the performance requirements (except for diameter) set forth by USP 24.

Mary Ann Greenawalt, Director
Regulatory and Quality

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary Ann Greenwalt
CP Medical
836 N. E. 24th Avenue
Portland, Oregon 97232

Re: K013274
Trade Name: Mono-Dox Synthetic Absorbable PDS Suture
Regulation Number: 878.4840
Regulation Name: Polydioxanone Suture
Regulatory Class: II
Product Code: NEW
Dated: September 28, 2001
Received: October 1, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

Susan Walker, MD

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

Enclosure

NOV 1 6 2001

510(k) Number: K013274

Device Name(s): ***Mono-Dox™***, Synthetic Absorbable Polydioxanone Suture, Sterile

Intended Use(s) of the Device:

Mono-Dox, Monofilament Synthetic Absorbable Sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery.
Mono-Dox suture is not indicated for use in adult cardiovascular tissue, microsurgery, and neural tissue. These sutures are useful where an absorbable suture with extended wound support (up to six weeks) is desirable.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walk

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

510(k) Number K013274

Prescription Use X or Over-The-Counter Use _____

(per 21 CFR 801.109) (Optional format 1-2-96)