MAR 2 8 2003

K030351

page 1/3

510 (k) Summary Report

Class II Special Controls Guidance Document, December 19, 2002

A. Establishment Name and Registration Number:

Establishment Name: CP MEDICAL, Inc.
Registration: 3032563
Owner/Operator: 9034828

B. Applicant's Name and Address:

CP MEDICAL, Inc.
836 NE 24th Avenue
Portland, Oregon 97232
Tel. 503-232-1555
Fax. 503-230-9993

C. Contact Person:

Mary Ann Greenawalt, VP Legal & Regulatory Affairs

D. Manufacturing Address:

CP MEDICAL, inc.
2414 NE Pacific Ave
Portland, Oregon 97232
Tel. 503-232-1555
Fax. 503-230-9993

E. Device Name:

Classification Name:
Stainless Steel Surgical Suture, non-Absorbable

Trade or Proprietary Name:
TBD

F. Classification Information:

Device Class: II
Classification Panel: General & Plastic Surgery Devices Panel
Product Code(s): GAQ

G. Performance/Recognized Standards: current USP standards

H. Labeling: *See Appendix I* for Packaging, Labeling, and Insert.

I. **Substantial Equivalence/Comparison Data:**

FEATURE	PREDICATE I	PREDICATE II	PROPOSED
Manufacturer	Davis & Geck	Ethicon	CP Medical
Indications for Use:	Indicated for use in abdominal wound closure, hernia repair, sternal closure and certain orthopedic procedures including cerclage and tendon repair.	Indicated for use in abdominal wound closure, hernia repair, sternal closure and certain orthopedic procedures including cerclage and tendon repair.	Indicated for use in abdominal wound closure, hernia repair, sternal closure and certain orthopedic procedures including cerclage and tendon repair.
Design:	Same	Same	Same
Sterile:	Same	Same	Same
Coloring:	N/A	N/A	N/A
Sizes:	USP Size 5, 6, 7	USP 5, 6, 7	USP Size 5, 6 7
Material:	316L Stainless steel suture 302, 420 or 420F needles	316L Stainless steel suture 302, 420 or 420F needles	316L stainless steel suture 302, 420 or 420F needles
Product Code:	GAQ	GAQ	GAQ
K - Number:	K955723	K931271	pending

CONFIDENTIAL

K030351
page 2/3

J. Device Description:

The CP Medical Stainless Steel Surgical Suture, monofilament, manufactured by C.P. Medical is equivalent to Nonabsorbable Surgical Sutures, Monofilament Stainless Steel manufactured by:

Davis-Geck
US Surgical
Danbury, C T 06810

Ethicon, Inc.
P O BOX 151
Somerville, NJ 08876-0151

C.P. Medical's proposed device is packaged as four (4) individual sutures inside one suture card. The four-unit suture card is placed into Tyvek and twelve Tyvek packs are inserted into a suture box. *See Packaging, Appendix I.* The suture may also be supplied in bulk on an OEM basis as requested via customer specifications. The suture is supplied sterile or non-sterile and is either Gamma Irradiated or EtO sterilized to the SAL of 10^{-6}. *See Appendix III.* The shelf life/expiration date is validated to five years from date of manufacture.

Please *see Appendix* II for Supplier Certification and Specifications of the Stainless Steel Surgical Suture Material. The risk analysis method used by CP Medical is FMEA and fault tree analysis.

USP Size 5 (metric 7.0), 6 and 7 (length 18") are primarily intended to be used for sternal closures. Additional sizes and lengths may be available in the future. All product is tested to USP standards prior to market release. The proposed device meets the requirements of ASTM F138-00 Gr.2 (Reg. Melt). Physical testing was performed on the predicate and proposed surgical sutures. Testing was performed using methods described in current USP for suture diameter, suture length, straight pull tensile strength and needle attachment strength. All sutures met or exceeded USP requirements. *See Technical Info, Appendix II.*

end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2003

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

Re: K030351
Trade/Device Name: Stainless Steel Surgical Suture
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: II
Product Code: GAQ
Dated: January 31, 2003
Received: February 3, 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

510(k) Number: K030351

Device Name(s): ***Stainless Steel Surgical Suture***

Indications for Use(s) of the Device:

Stainless Steel Surgical Suture is indicated for use in abdominal wound closure, hernia repair, sternal closure and certain orthopedic procedures including cerclage and tendon repair.

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 K030351

Prescription Use X or Over-The-Counter Use _____

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

[redacted]