K023710

JAN 17 2003

510(K) SUMMARY

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

Device Name:

Trade Name: *VISORB Swift*™

Common Names; Absorbable suture, synthetic absorbable suture, PGA suture

Classification Names: 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

Contact: Mary Ann Greenawalt (VP Legal & Regulatory)
or
Sue Ridge (Technical Writer – Regulatory)

Classification:

Device Class: Class ll

Classification Panel: General & Plastic Surgery

Product Code: 79GAM

Intended Use:

VISORB Swift™ Absorbable Surgical Sutures are indicated for use in general soft tissue approximations, including use in ophthalmic surgery, but not for use in cardiovascular and neurological tissue approximation.

Equivalent Predicated Device:

VISORB Swift™ synthetic absorbable suture is substantially equivalent to the predicate devices marketed by Ethicon and B/BRAUN. The comparison data demonstrates that equivalency can be drawn with respect to the design, material composition, performance and intended use.

Performance Standard:

VISORB Swift™ meets or exceeds the performance requirements set forth by USP 25.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

CP Medical
Mary Ann Greenawalt
Legal and Regulatory Affairs
836 N.E. 24th Avenue
Portland, Oregon 97232

Re: K023710
Trade/Device Name: VISORB Swift™
Regulation Number: 878.4840
Regulation Name: Synthetic, absorbable suture, polyglycolic acid
Regulatory Class: Class II
Product Code: GAM
Dated: November 1, 2002
Received: November 4, 2002

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. 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,

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: K023710

Device Name(s): ***VISORB Swift™***

Intended Use(s) of the Device:

General soft tissue approximation; including use in Ophthalmic surgery, but not for use in Cardiovascular and Neurological tissue approximation.

Miriam C. Provost

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

510(k) Number K023710

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use _____

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