K072229

CP Medical
Portland, OR USA

OCT 5 2007

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Device Name:	Monoswift™ Synthetic Absorbable Suture
Device Model Number:	"Lxxx" series
Classification Name:	Absorbable Suture, Synthetic, Polyglycolic Acid (GAM)
Device Classification:	Class II, 21 CFR 878.4493
Predicate Devices:	CP Medical Visorb, K002190 Ethicon Monocryl, K960053 (dyed) , K964072 (undyed)
Manufacturer:	CP Medical 803 NE 25th Ave. Portland, OR 97232 USA
Establishment Registration Number:	3032563
Official Contact:	Betsy Cortelloni Regulatory Affairs Manager Theragenics Corporation® 5203 Bristol Industrial Way Buford, GA 30518 Phone: 770-271-0233 Fax: 770-831-4369

Intended Use: Monoswift™ is a monofilament, synthetic absorbable suture indicated for use in soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery, microsurgery, or ophthalmic surgery.

Device Description: Monoswift™ is a monofilament, synthetic absorbable suture indicated for use in soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery, microsurgery, or ophthalmic surgery.

Substantial Equivalence Comparison: Monoswift™ performance for the intended use is similar to that of other PGCL sutures in that it is a monofilament, synthetic absorbable surgical suture comprised of poly(glycolic co-caprolactone) and may be dyed with D&C Violet #2. Breaking strength retention is consistent with the predicate PGCL sutures.

Design Verification: The testing and verification activities performed for this product demonstrate that the product complies with USP requirements for needle attachment tensile strength.

Conclusion: The results of verification testing confirmed that design inputs were achieved and that Monoswift™ is substantial equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CP Medical
% Theragenics Corporation
Ms. Betsy Cortelloni
Regulatory Affairs Manager
5203 Bristol Industrial Way
Buford, Georgia 30518

OCT 5 ° 2007

Re: K072229
Trade/Device Name: Monoswift™ Synthetic Absorbable Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly (glycolide/L-lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: August 9, 2007
Received: August 10, 2007

Dear Ms. Cortelloni:

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.

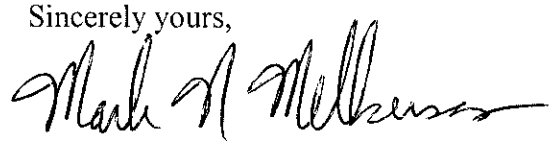
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O.
f/t:NOH:kxl:10-03-07

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices Br	240-276-0120

K072229

INDICATIONS FOR USE FORM

510(K) number (if known): K072229

Device Name: MonoSwift™

Indications for Use:

Monoswift™ is a monofilament, synthetic absorbable suture indicated for use in soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery, microsurgery, or ophthalmic surgery.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use_____
(Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K072229