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CP Medical
Portland, OR USA

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

MAR 18 2010

Device Name:	CP-Fiber (OrthoFiber®)
Device Model Number:	"CPF" and "BCPF" series
Common or Usual Name:	Non-Absorbable Suture, Synthetic, Polyblend
Classification Name:	GAT, Non-Absorbable Suture, Synthetic, Polyethylene
Device Classification:	Class II, 21 CFR 878.5000
Predicate Devices:	K041894 – CP-Fiber (proprietary name OrthoFiber®) from CP Medical, Inc. K040004 – ORTHOCORD™ Suture from Depuy Mitek K021434 – Arthrex FiberWire® from Arthrex, Inc. K063778 – Force Fiber® from Teleflex, Inc.
Date:	12/24/09
Manufacturer:	CP Medical, Inc. 803 NE 25th Ave. Portland, OR 97232 USA
Establishment Registration Number:	3032563
Official Contact:	Barbara Keller Horton Director of Quality and Regulatory Affairs CP Medical Phone: 503-232-1555 Fax: 503-230-9993

Intended Use: CP-Fiber is indicated for use in soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neurological, and orthopedic surgeries.

Device Description: CP-Fiber is a synthetic non-absorbable suture composed of a braided polyblend. As with all surgical sutures, CP-Fiber is a single-use device. This submission expands the indications for use to include orthopedic surgeries.

Substantial Equivalence Comparison: CP-Fiber is substantially equivalent in intended use and device characteristics to products already on the market in the same product category.

Technological Characteristics: The product is unchanged from the predicate device. Testing activities demonstrate that the product complies with USP requirements for non-absorbable sutures.

Conclusion: This submission demonstrates that CP-Fiber is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CP Medical, Inc
% Ms. Barbara Keller Horton
Director of Quality and Regulatory Affairs
803 NE 25th Avenue
Portland, Oregon 97232

MAR 18 2010

Re: K094028
Trade/Device Name: CP-Fiber
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: March 31, 2010
Received: April 12, 2010

Dear Ms. Horton:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

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INDICATIONS FOR USE

510(K) number (if known):_____

Device Name: CP-Fiber

Indications for Use:

CP-Fiber is indicated for use in soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neurological, and orthopedic surgeries.

Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krone for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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