K033718

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ARTHROTEK®

A Biomet Company

CORPORATE HEADQUARTERS

510(k) Summary

Applicant/Sponsor: Arthrotek, Inc.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.

Proprietary Name: MaxBraid™ Polyester Plus and Polyethylene Plus Suture

Classification Name: Suture, nonabsorbable, synthetic, polyethylene (21 CFR 878.500)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Arthrex FiberWIRE™ - K010673 (Arthrex, Inc.) and Polyester Nonabsorbable Surgical Suture - K001172 (CP Medical)

Device Description: Two configurations of MaxBraid™ suture are included in this submission. The first consists of a polyester core with a braided polyethylene and polyester outer layer with the trade name of MaxBraid™ Polyester Plus Suture. The second type consists of a polyethylene core with a braided polyethylene and polyester outer layer with the trade name of MaxBraid™ Polyethylene Plus Suture. Both types are supplied in lengths of 38" with or without attached suturing needles. The suture is size 2 in keeping with currently recognized United States Pharmacopoeia (USP) standards. Both white and blue suture will be marketed. The suture is coated with silicone in order to ease passage through tissue. When desired, the MaxBraid™ Polyester Plus and Polyethylene Plus Suture may be used with a commercially available suture anchor.

Intended Use: MaxBraid™ Polyester Plus and Polyethylene Plus Sutures are indicated for general soft tissue approximation and/or ligation

Summary of Technologies: The overall design, materials and processing are similar to the predicate device.

Non-Clinical Testing: Testing demonstrated that MaxBraid™ Suture met or exceeded the USP 24 standards for nonabsorbable sutures and are substantially equivelent to the predicate devices.

Clinical Testing: None provided

All trademarks are property of Biomet, Inc.
FiberWIRE is a trademark of Arthrex, Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2004

Arthrotek, Inc.
c/o Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0578

Re: K033718
Trade/Device Name: MaxBraid™ Polyethylene Plus and Polyester Plus Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: November 25, 2003
Received: November 26, 2003

Dear Ms. Beres:

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). 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) 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

Indications for Use

510(k) Number (if known): K033718

Device Name: MaxBraid™ Polyethylene Plus and Polyester Plus Suture

Indications For Use: MaxBraid™ Polyethylene Plus and Polyester Plus suture is indicated for general soft tissue approximation and/or ligation

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K033718