SEP 25 2006

510(k) Summary

Preparation Date: September 25, 2006

Applicant/Sponsor: Arthrotek, Inc. (a wholly owned subsidiary of Biomet, Inc.)

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

Proprietary Name: Arthrotek® Maxfire™ Meniscal Repair Device

Common Name: Suture Anchor

Classification Name: Bone Fixation Appliances and Accessories (21 CFR 888.3030)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
K041988 - Arthrotek® Meniscal Hybrid Device (Biomet Manufacturing Corp.)
K040472 - Force Fiber Blue Co-Braid Polyethylene Non-Absorbable Surgical Suture (Teleflex Medical)

Device Description: The Arthrotek® Maxfire™ Meniscal Repair Device is a permanent fixation anchor composed of 2-0 Maxbraid™ ultra-high molecular weight polyethylene/polypropylene suture (Teleflex Medical, K040472) covered with two non-resorbable polyester or polyethylene sleeves. The anchors are pre-loaded on to an insertion instrument. The inserter allows for single entry into the joint. Once in the joint, the inserter will pierce the meniscus at the desired location. A pusher within the handle of the inserter allows separate deployment of the anchors, one on each side of the tear. After the second anchor has been deployed, the free ends of suture are gently pulled by the surgeon, drawing the loops into a flat, donut-shaped ring. This anchor sits on the backside of the meniscus. The suture is covered with either a polyester or polyethylene sleeve in order to control the size of the knot thus ensuring that the anchor does not become too small and pull through the meniscal tissue. By tensioning the suture, a sliding knot allows the meniscal tear to be compressed.

Intended Use: The Arthrotek® Maxfire™ Meniscal Repair Device is indicated for the repair of vertical longitudinal full thickness tears (i.e. bucket-handle) in the red-red and red-white zones. These devices are not to be used for meniscal tears in the avascular zones of the meniscus.

Summary of Technologies: The Arthrotek® Maxfire™ Meniscal Repair Device has similar technologies to the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

All trademarks are property of Biomet, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arthrotek, Inc.
% Biomet Manufacturing Corporation
Ms. Patricia Sandborn Beres
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56 E. Bell Drive
Warsaw, Indiana 46581-0587

SEP 25 2006

Re: K061776
Trade/Device Name: Arthrotek® Maxfire™ Meniscal Repair Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR, HWC
Dated: September 11, 2006
Received: September 13, 2006

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.

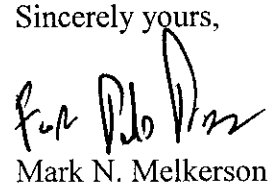
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

510(k) Number (if known): K061776

Device Name: Arthrotek® Maxfire™ Meniscal Repair Device

Indications For Use:

The Arthrotek® Maxfire™ Meniscal Repair Device is indicated for the repair of vertical longitudinal full thickness tears (i.e. bucket-handle) in the red-red and red-white zones. These devices are not to be used for meniscal tears in the avascular zone of the meniscus.

Prescription Use X AND/OR Over-The-Counter Use NO
(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)

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

510(k) Number K061776