K041988 Pg 1 of 2

OCT 2 0 2004

510(k) Summary

Applicant/Sponsor: Arthrotek. Inc.
(A wholly owned subsidiary of Biomet, Inc.)
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639

Proprietary Name: Arthrotek® Meniscal Hybrid Device

Common Name: Meniscal Repair Device

Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue 21 CFR §888.3045

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

* K982095 Lactosorb® Meniscal Repair Device - Biomet Inc., Warsaw, IN
* K965228 Surgical Dynamics Meniscal Staple – U.S. Surgical, Norwalk, CT

Device Description:
The Arthrotek® Meniscal Hybrid Device incorporates two toggle anchors attached by two suture loops, one suture loop containing a sliding knot. The toggle anchors are approximately 7mm long and have beveled tips on each end. Incorporated into the body of the toggle anchor is an eyelet for the suture to pass through. They are constructed of Lactosorb®, a bio-resorbable copolymer of PLLA/PGA

Intended Use:
The Arthrotek® Meniscal Hybrid 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.

Summary of Technologies:
The Arthrotek® Meniscal Hybrid Device toggle anchors are manufactured from the same Lactosorb® PLLA/PGA copolymer as the predicate Meniscal Repair Device (K982095).

Non-Clinical Testing:
Mechanical testing found the Arthrotek® Meniscal Hybrid Device to be substantially equivalent in pullout strength, to the predicate Meniscal Repair Device (K982095).

Clinical Testing:
Clinical testing was not required for these components to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2004

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581

Re: K041988
Trade/Device Name: Arthrotek® Meniscal Hybrid 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, MAI
Dated: July 22, 2004
Received: July 23, 2004

Dear Mr. Baker:

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.

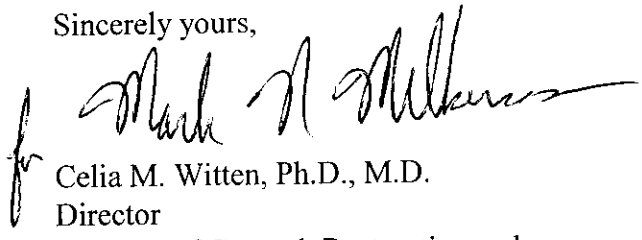
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21CFR Part 807.97) you may obtain. 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,



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): K041988

Device Name: Arthrotek® Meniscal Hybrid Device

Indications For Use:

The Arthrotek® Meniscal Hybrid 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 ___N/A___
(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)

for Mark N Melkerson

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

510(k) Number K041988