NOV 2 0 2001

BIOMET INC
CORPORATE HEADQUARTERS

SUMMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor:

Arthrotek, Inc.
(A wholly owned subsidiary of Biomet, inc.)
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
Establishment Registration No.: 1825034

Contact Person:

Sara B. Shultz
Biomet Manufacturing, Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (219) 267-6639
FAX: (219) 372-1683

Proprietary Name: Resorbable Screw Anchor

Common or Usual Name: resorbable screw anchor

Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue

Device Product Code: 87MAI

Legally Marketed Devices To Which Substantial Equivalence is Claimed:
Harpoon Suture Anchor (Biomet, Inc., K943806/K973775), LactoSorb® Suture Anchor (Biomet, Inc., K954443), LactoSorb® Screw Anchor (Biomet, Inc., K003273), Resorbable Bone Pin (Biomet, Inc., K011522).

Indications for Use: Indications for the Resorbable Screw Anchor includes use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications are as follows:

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.
Wrist/Hand: Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.
Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

00241

SHIPPING ADDRESS
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Elbow: Tennis elbow repair, ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.
Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair.

Device Description: The Resorbable Screw Anchor is a screw-type anchor used to provide means for attaching soft tissue to bone during healing. The device is manufactured from an 85% L-Lactide/15% Glycolide material and is available in two sizes, 3.5 mm and 5.5 mm. The screw anchor consists of a screw portion and a head portion.

The 3.5 mm size anchor will be available with a monofilament suture, #1 suture, or #2 suture while the 5.5 mm size anchor will be available with a monofilament suture, two #2 sutures or a #5 suture. The Resorbable Screw Anchor will be packaged sterile and will be preloaded on a driver with suture.

Summary of Technologies: The Resorbable Screw Anchor's technological characteristics (materials, design, sizes, and indications) are similar to or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

Ms. Sara B. Shultz
Regulatory Specialist
Arthrotek, Inc.
A Subsidiary of Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K012872
Trade/Device Name: Resorbable Screw Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: II
Product Code: HWC
Dated: August 25, 2001
Received: August 27, 2001

Dear Ms. Shultz:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 2 0 2001

510(k) NUMBER (IF KNOWN): K012872

DEVICE NAME: Resorbable Screw Anchor

INDICATIONS FOR USE:

Indications for the Resorbable Screw Anchor include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications are as follows:

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.
Wrist/Hand: Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.
Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.
Elbow: Tennis elbow repair, ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.
Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair.

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012872

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter-Use No (Optional Format 1-2-96)