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BIOMET
ORTHOPEDICS, INC.

JUL 19 2006

510(k) Summary

Preparation Date: **May 15, 2006**

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: Lester F. Padilla

Proprietary Name: ALLthread™ LactoSorb® Suture Anchor

Common Name: Suture anchor

Classification Name: Fastener, fixation, biodegradable, soft tissue (21 CFR 888.3030)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- LactoScrew™ Screw Anchor (K033355)

Device Description: The ALLthread™ LactoSorb® Suture Anchor is made with an L-Lactide / Glycolide resorbable material, preloaded with #2 polyethylene surgical sutures. The design will enable the anchor to be inserted either without pre-drilling or through a pre-drilled hole.

Intended Use: Indications for the ALLthread™ LactoSorb® Suture 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, acromioclavicular separation repair, 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, Halluxvalgus reconstruction, mid- and forefoot reconstruction.

Elbow: Tennis elbow repair, Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction.

Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, patellar ligament/tendon repair.

Summary of Technologies: The ALLthread™ LactoSorb® Suture Anchors have similar or identical technological characteristics (design, materials, functional performance) as the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicate that the anchors are substantially equivalent to predicate anchors with similar indications for use.

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

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Warsaw, IN 46582

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574.267.6639

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574.267.8137

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biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2006

Arthrotek, Inc.
% Mr. Lester F. Padilla
Regulatory Affairs Associate
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K061389
Trade/Device Name: Allthread™ LactoSorb® Suture Anchor
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: May 15, 2006
Received: May 18, 2006

Dear Mr. Padilla:

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.

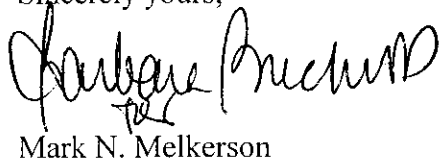
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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): K061389

Device Name: ALLthread™ LactoSorb® Suture Anchor

Indications for Use:

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

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Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, patellar ligament/tendon repair.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___NO___ (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)

Barbara Buchman for MM

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

510(k) Number K061389