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K032072

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BIOMET
ORTHOPEDICS, INC.

510(k) Summary

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Tracy J. Bickel
Telephone: (574) 267-6639
Fax: (574) 372-1683

Proprietary Name: LactoSorb® Screw Anchor with Lactocarbonate Suture

Common Name: Resorbable Suture and Screw

Classification Name: Fastener, Fixation, Biodegradable Soft tissue; 87 MAI

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Biomet's LactoSorb® L15 Screw Anchor (K012872), Ethicon's Mitek Panalok Suture Anchor System (K970396), and Biomet's LactoSorb® L18 Screw Anchor (K003273).

Device Description:
The LactoSorb® Screw Anchor's are resorbable suture anchors used to reattach soft tissue to bone. The anchors consist of a screw portion and a head portion. The screw portion engages with the bone while the head portion provides a means to drive the anchor into the bone.

Lactocarbonate Suture, undyed (white) or dyed (violet), is a synthetic resorbable sterile surgical suture. The suture is a braided size 2 suture.

Intended Use:
Indications for the LactoSorb® Screw Anchor with Lactocarbonate Suture includes the 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 repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair.

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

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639 ■ FAX
574.267.8137 ■ E-MAIL
biomet@biomet.com

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

Non-Clinical Testing: Nonclinical laboratory testing was performed to determine substantial equivalence. Biocompatibility and Functionality testing was conducted to assess the safety and effectiveness of Lactocarbonate suture (L-lactide / trimethylene carbonate, dyed and undyed. Results indicated that the device was highly biocompatible and was functional within its indicated uses.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2003

Arthrotek, Inc.
c/o Ms. Tracy J. Bickel
Regulatory Associate
Biomet Orthopedic, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K032072
Trade/Device Name: LactoSorb® L15 Screw Anchor with Lactocarbonate Suture
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 1, 2003
Received: July 3, 2003

Dear Ms. Bickel:

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, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032072
Device Name: **LactoSorb® Screw Anchor with Lactocarbonate Suture**
Indications for Use:

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

510(k) Number K032072

(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)