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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

Contact Person:

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

Proprietary Name: Resorbable LactoSorb-L® ACL Crosspin

Common or Usual Name: Pin

Classification Name: Pin, Fixation, Smooth, Non-metallic (888.3040)

Device Product Code: HTY and MAI

Legally Marketed Devices To Which Substantial Equivalent Is Claimed: Arthrotek Interference Screw (K988497), Mitek 3.3 ST Cross Pin (K974341), Bone Mulch Screw (K K941941/K991298/K993025), Arthrex Bio-Transfix (K011172).

Indications for Use: The Resorbable LactoSorb-L® ACL Crosspin is indicated for ACL reconstruction.

Device Description: The Resorbable LactoSorb-L® ACL Crosspin is comprised of a PLLA:PGA copolymer. The threadless, push-in device is used for femoral fixation of a soft tissue graft.

The Resorbable LactoSorb-L® ACL Crosspin includes a suture eyelet at the tip. This eyelet allows the device to be used with a technique similar to that utilized by cannulated devices, however, the crosspin is not cannulated.

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

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

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

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

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2002

Ms. Sara B. Shultz
Regulatory Specialist
Arthrotek, Inc.
C/O Biomet Orthopedics
P.O. Box 587
Warsaw, IN 46581

Re: K014305
Trade/Device Name: Resorbable LactoSorb-L® ACL Crosspin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: December 28, 2001
Received: December 31, 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, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K014305

DEVICE NAME: Resorbable LactoSorb-L® ACL Crosspin

INDICATIONS FOR USE:

The Resorbable LactoSorb-L® ACL Crosspin is indicated for ACL reconstruction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number K014305