JUN 2 6 2002

BIOMET
CORPORATE HEADQUARTERS

## SUMMARY 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.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46582
Phone: (574) 267-6639
FAX: (574) 372-1683

**Proprietary Name:**

Arthrotek Resorbable No-Profile LactoSorb® L-15 Screw and Washer

**Common Name:**

Resorbable screw and washer

**Classification Name:**

Screw, Fixation, Bone, Non-spinal, Non-metallic (888.3040)
Washer, Bolt Nut, Non-spinal, Non-metallic (888.3030)

**Device Product Code:**

87HWC and HTN

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**
Resorbable No Profile Screw and Washer, Biomet, Inc. (K012469).

**Intended Use:** The Arthrotek Resorbable No-Profile LactoSorb® L-15 Screw and Washer is indicated for the following procedures:

1. ACL and PCL reconstruction
2. Medial collateral ligament repair
3. Lateral collateral ligament repair
4. Posterior oblique ligament repair
5. Iliotibial band tenodesis reconstruction
6. Patellar ligament and tendon repair

This device is also intended to be used as back-up fixation in ACL reconstruction in conjunction with other marketed devices in order to provide additional fixation strength in instances of questionable bone quality.

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

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**Device Description:** The Arthrotek Resorbable No-Profile LactoSorb® L-15 Screw and Washer consists of a resorbable 6.5 mm screw that varies in length from 25 mm to 55 mm (5 mm increments) and a 18 mm diameter washer with eight spikes on the distal surface. The screw is machined from an 85% L-Lactide/15% Glycolide material that is a high viscosity copolymer. The washer is injection molded from the same material.

**Non-Clinical Testing:** Non-clinical testing demonstrated statistical equivalence between this device and the predicate.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2002

Ms. Sara B. Shultz
Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K021832
Trade/Device Name: Arthrotek Resorbable No-Profile LactoSorb® L-15 Screw and Washer
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 3, 2002
Received: June 4, 2002

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 Mark N. Melkerson

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

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.

f/t: POSung:bxw:6/25/02

510 (k) Number (if known) : K021832

DEVICE NAME: Arthrotek Resorbable No-Profile LactoSorb® L-15 Screw and Washer

INDICATIONS FOR USE:

The Arthrotek Resorbable No-Profile LactoSorb® L-15 Screw and Washer is indicated for the following procedures:

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This device is also intended to be used as back-up fixation in ACL reconstruction in conjunction with other marketed devices in order to provide additional fixation strength in instances of questionable bone quality.

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

510(k) Number K021832

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use NB (Optional Format 1-2-96)