K053461 page 1 of 1

BIOMET

FEB 3 2006

510(k) Summary

Applicant/Sponsor: Arthrotek, Inc.

Contact Person: Susan Alexander

Proprietary Name: EZLoc™ Femoral Fixation Device

Common Name: Soft tissue anchor

Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue (888.3040)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Titanium Toggle Button (K033838) and Femoral Hook (K041261)

Device Description: The EZLoc™ Femoral Fixation Device is the same design as the predicate Femoral Hook (EZLoc™), cleared in K041261, with additional sizes. The device includes a body, an arm, a passing pin and a pull suture. The implant will be available in three diameters: 5-6mm, 7-8mm and 9-10mm; and five lengths: 15mm, 20mm, 25mm, 30mm and 35mm. The sizes will account for the varying diameters and lengths of the replacement graft and femoral tunnel length. Currently the devices are packaged with a #2 polyethylene suture, but may also be used with any legally marketed, nonresorbable suture.

Intended Use: Fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) reconstruction.

Summary of Technologies: The technological characteristics (material, design, sizing, indications) of the EZLoc™ Femoral Fixation Device are similar to or identical to the predicate devices. The EZLoc™ Femoral Fixation Device has been modified to include new sizes.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

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

All trademarks are property of Arthrotek, Inc., a wholly-owned subsidiary of Biomet, Inc.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Ms. Susan Alexander
Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K053461
Trade/Device Name: EZLoc™ Femoral Fixation
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: December 12, 2005
Received: December 13, 2005

Dear Ms. Alexander:

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), 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) you may obtain. 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,

Mark N. Melkerson
Acting 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): K053461

Device Name: EZLoc™ Femoral Fixation Device

Indications For Use:

Fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) reconstruction.

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

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

(510(k) Number K053461