K040500

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MAY 25 2004

ARTHROTEK®

A BIOMET COMPANY

CORPORATE HEADQUARTERS

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Tracy J. Bickel, RAC
Regulatory Associate

Proprietary Name: Arthrotek® LactoNail™

Common Name: resorbable bone fixation nail

Classification Code: HTY

Classification Name: Pin, Fixation, Smooth (888.3040)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
SmartPin™ (Bionx Implants) - K925098

Device Description: The Arthrotek® LactoNail™ bioabsorbable bone fixation nail is constructed of a resorbable copolymer composed of PLLA/ PGA. The device is available in 1.6, 2.0, and 2.6mm diameters. The LactoNail™ comes in four (4) lengths (14, 18, 22, and 26mm). Arthrotek® LactoNail™ maintains alignment of small bone fractures and apical fragments, osteochondral fragments and cancellous/non-load bearing fragments following arthroscopy or open surgery.

Indications for Use: The Arthrotek® LactoNail™ is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies, and arthrodesis. Examples include the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

Summary of Technologies: The Arthrotek® LactoNail™ is similar to or identical in terms of material, function, labeling, and sizing to the predicate SmartPin™ (K925098).

Non-Clinical Testing: Mechanical testing was performed on the Arthrotek® LactoNail™ comparing it to the predicate device (K925098). The testing demonstrates that the Arthrotek® LactoNail™ is substantially equivalent to the predicate.

Clinical Testing: Clinical testing was not required for this product.

MAILING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE 219.267.6639 ■ E-MAIL arthrotek@arthrotek.com ■ FAX 219.372.1718

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2004

Ms. Tracy J. Bickel, RAC
Regulatory Associate
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581

Re: K040500
Trade/Device Name: Arthrotek® LactoNail™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: February 25, 2004
Received: February 27, 2004

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), 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,

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

Indications for Use

510(k) Number (if known): K040500

Device Name: Artrhotek® LactoNail™

Indications For Use:

The Arthrotek® LactoNail™ is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies, and arthrodesis. Examples include the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

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)

for Mark N. Milleson

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

510(k) Number K040500