K063570

FEB 27 2007

510(k) Summary

Preparation Date:	November 28, 2006
Applicant/Sponsor:	Biomet Trauma (aka EBI; names may be used interchangeably) 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Becky Earl/Debra L. Bing
Proprietary Name:	Biomet® Tibial Locking Nail System
Common Name:	Titanium intermedullary nails
Classification Name:	Rod, Fixation, Intramedullary and Accessories (CFR 888.3020)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Titanium Intramedullary Rods—Various (Uniflex® Tibial Nail (Low Profile) – K982953 (Biomet Inc.)

Device Description:
The Biomet® Tibial Locking Nail System is an intramedullary nail, designed to be inserted through the proximal tibia and proceed down the intramedullary canal of the tibia. The nail has both a proximal and distal bend to accommodate the anatomy of the tibia. Features include an internal locking/compression mechanism, a dynamization/locking slot, and numerous screw configurations to enable nail fixation.

Intended Use:
The Biomet® Tibial Locking Nail System is indicated for alignment, stabilization, fixation of fractures caused by trauma or disease, and the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity and arthrodesis.

Summary of Technologies:
The technological characteristics (materials, design, sizing, aritculating surface, indications) of the Biomet® Tibial Locking Nail System are similar or identical to the predicate device.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp.
c/o Ms. Becky Earl
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581

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Re: K063570
Trade/Device Name: Biomet® Tibial Locking Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 28, 2006
Received: November 29, 2006

Dear Ms. Earl:

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.

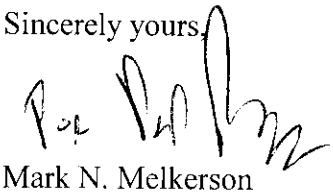
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
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):_____

Device Name: Biomet® Tibial Locking Nail System

Indications For Use:

The Biomet® Tibial Locking Nail System is indicated for alignment, stabilization, fixation of fractures caused by trauma or disease, and the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity and arthrodesis.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (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,
and Neurological Devices

510(k) Number K023510