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AUG 26 2002

Summary of Safety and Effectiveness
Titanium Ankle Arthrodesis Nail

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Lonnie Witham
Telephone: (574) 267-6639
Fax: (574) 372-1683

Proprietary Name: Titanium Ankle Arthrodesis Nail

Common Name: Titanium Intramedullary Nail (Rod)

Classification Name: Intramedullary Rods (21 CFR 888.3020)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed:
These devices are substantially equivalent to Biomet Titanium Intramedullary Nails previously cleared in K982953.

Device Description: Intramedullary rods made of titanium alloy are used for the same indications as stainless steel intramedullary rods that have been commercially available continually since the 1950s. These devices are to be implanted by insertion into the long bones for fixation of fractures, or the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity, or arthrodesis. Transverse screws can be used to further stabilize bone fragments distally and proximally, as needed. A wide variety of titanium intramedullary nails indicated for used in long bones (femur, tibia, fibula, humerus, radius, and ulna were cleared for commercial distribution in Biomet 510(k) premarket notification (K982953).

These ankle arthrodesis nails have the same general intended use (arthrodesis, internal fixation of bone), warnings and precautions as those nails previously cleared in K982953. The standard arthrodesis nails are10, 11, and 12 mm in diameter in 15 mm and 18 cm lengths. Longer lengths will be made upon request (up to 46 cm length). The longer nails will be used to treat patients who may require revision of a previously implanted arthrodesis nail due to tibial fracture. Substantially similar titanium femoral and tibial nails in 8, 9, 10, 11, 12, 13 and 14 mm diameters up to 46 cm in length were previously cleared in K982953.

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Intended Use: The Titanium Ankle Arthrodesis Nail is intended for tibiotalocalcaneal arthrodesis (fusion). The process of tibiotalocalcaneal arthrodesis using an intramedullary nail usually involves an ankle arthrotomy, preparation of the joint surfaces, and then placement of the nail through a plantar incision. Screws are placed proximally into the tibia in a standard fashion and, after compression, the nail can be locked distally with screws into the calcaneus and the talus.

Indications for Use

The indications for tibiotalocalcaneal arthrodesis include:

1. Avascular necrosis of the talus
2. Failed total ankle arthroplasty
3. Trauma (malunited tibial pilon fracture)
4. Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
5. Revision ankle arthrodesis
6. Neuroarthropathy
7. Rheumatoid arthritis
8. Osteoarthritis
9. Pseudoarthrosis

Summary of Technology: This device utilizes standard technology that is commonly known by physicians. This technology has been used in commercially available metallic internal fixation devices prior to May 28, 1976. This particular device is a tubular metal rod that is inserted through the talus and into the medullary canal of the tibia to stabilize bone fragments until healing has occurred.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2002

Lonnie Witham
Biomet, Inc.
P. O. Box 587
Warsaw, Indiana 46581- 0587

Re: K021786
Trade/Device Name: Titanium Ankle Arthrodesis Nail
Regulatory Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB
Dated: May 10, 2002
Received: May 30, 2002

Dear Mr. Witham:

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 Milhern

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

AUG 2 6 2002

STATEMENT OF INDICATIONS FOR USE

510(k) Number K021786

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

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510(k) Number K021786