

OCT 21 1998

**BIOMET<sup>®</sup>**  
CORPORATE HEADQUARTERS

**Summary of Safety and Effectiveness**

**Sponsor.** Biomet, Inc.  
Airport Industrial Park  
P.O. Box 587  
Warsaw, Indiana 46581

**Device.** Titanium Intramedullary Rods – Various Styles

**Classification Name.** Rod, Fixation, Intramedullary and Accessories (CFR 888.3020)

**Device Description.** Intramedullary rods are generally rod-shaped devices with or without screw holes at either end for fixation to bone. These devices are intended to be inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures by aligning and stabilizing the bone fragments. Intramedullary rods are also used to align and stabilize long bones which are surgically cut (osteotomy) to correct deformity. Additional stabilization may be realized by installing transverse screws through holes in the rod. Intramedullary rods and transverse screws are made of titanium 6Al-4V alloy.

Intramedullary rods are used in the femur, tibia, fibula, humerus, radius, and ulna.

**Potential Risks.** The risks associated with this device are the same as with any metallic internal fixation device. These include but are not limited to the following.

Delayed or nonunion which may lead to breakage of the implant

Bending or fracture of the implant

Loosening or migration of the implant

Metal sensitivity, or allergic reaction to a foreign body

Limb shortening or decrease in bone density due to compression of the fracture or bone resorption

Pain, discomfort, or abnormal sensations due to the presence of the device

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219.267.6639

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219.267.8137

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biomet@biomet.com

000093

Nerve damage due to surgical trauma

Necrosis of bone

Infection

Hematoma

**Substantial Equivalence.** In function and overall design, titanium intramedullary rods are equivalent to stainless steel intramedullary rods which have been widely used for fracture fixation in long bones since the 1960s.

Grosse Kempf System (Howmedica)

Intramedullary Nails (Zimmer)

Kirschner Intramedullary Nail System (now Biomet, Inc.)

OEC Kuntscher Cloverleaf Nail Systems (now Biomet, Inc.)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 21 1998

Mr. Lonnie Witham  
Senior Regulatory Affairs Specialist  
Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K982953  
Titanium Intramedullary Nails - Various Styles  
Regulatory Class: II  
Product Code: HSB  
Dated: August 18, 1998  
Received: August 24, 1998

Dear Mr. Witham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

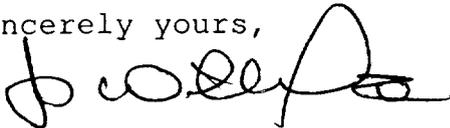
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Lonnie Witham

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
f 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

510(k) Number: K982953

Device Name: Titanium Intramedullary Nails

**Indications For Use:** 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 into the long bones for alignment, stabilization and fixation of fractures caused by trauma or disease, the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity, and for arthrodesis. Intramedullary rods are used in the femur, tibia, fibula, humerus, radius, and ulna.

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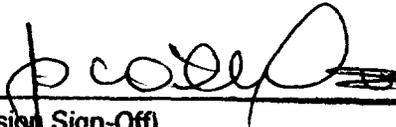
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X    
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number           K982953