

K993956

DEC 20 1999

Summary of Safety and Effectiveness Information

Sponsor: Biomet, Inc.

Airport Industrial Park

P.O. Box 587

Warsaw, Indiana 46580

Device: Titanium Pediatric Femoral Nail

Classification Name: Rod, Fixation, Intramedullary and Accessories (21 CFR 888.3020)

Device Description: Intramedullary rods (nails) are generally rod-shaped devices, with or without screw holes at either end for fixation to bone. This device is intended to be inserted into the medullary (bone marrow) canal of the femur for fixation of fractures by aligning and stabilizing the bone fragments. Additional stabilization may be realized by installing transverse screws through holes in the rod. This device is made of titanium 6AL-4V alloy.

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 non-union that may lead to breakage of the implant

Bending, fracture, 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

Nerve damage due to surgical trauma

Necrosis of bone

Infection

Hematoma

Substantial Equivalence: In function and overall design, titanium intramedullary rods (nails) are equivalent to stainless steel rods that have been widely used for fracture fixation of long bones since the 1960's. In addition, a wide variety of titanium intramedullary rods (nails) were cleared for commercial distribution under Biomet 510(k) number K982953 for use in the femur, tibia, fibula, humerus, radius, and ulna.

Biomet/OEC Stainless Steel Flexible Nails
Biomet Titanium Intramedullary Rods (K982953)



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993956
Trade Name: Titanium Pediatric Femoral Nail
Regulatory Class: II
Product Code: HSB
Dated: November 12, 1999
Received: November 22, 1999

Dear Ms. 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.

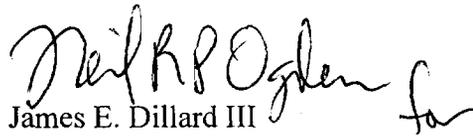
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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 premarket 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.

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) 594-4595. 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,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is written in a cursive style with a large initial "J" and a long, sweeping tail.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K993956

Device Name: Titanium Pediatric Femoral Nail

Indications for Use:

The Titanium Pediatric Femoral Nail is indicated for fractures of the femur including: non-comminuted and comminuted mid-shaft fracture, combination fractures of the shaft and neck, intertrochanteric fracture, combination intertrochanteric and subtrochanteric fractures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

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

Division Sign Off _____ *TRO for*
Division _____
510(k) Number K993956