

K983641

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
Airport Industrial Park
Warsaw, Indiana 46580

Device: Holland Femoral Nail System

Classification Name: Intramedullary fixation rod

Intended Use: 1) fresh fractures of the femur to include; non-comminuted midshaft fractures, subtrochanteric fractures, distal third fractures, combination fractures of the shaft and neck, intertrochanteric fractures, combination intertrochanteric and subtrochanteric fractures. 2) osteotomy and reconstructive procedures following tumor resection. 3) revision procedures where other treatments or devices have failed. 4) arthrodesis.

This device is a single use implant.

Device Description: The Holland Titanium Femoral Nail is an interlocking intramedullary rod used in the fixation of fractures of the femur. The nail consists of four basic components, TI-Cannulated cancellous screws, TI-pilot threaded screws, Ti-cannulated end cap extensions, and the TI-femoral recon nail.

The nail is a solid titanium alloy component, available in both right and left configurations and one universal nail. Proximally the nail has an 8 degree offset enabling the surgeon to insert the nail through a more lateral insertion point -the greater trochanter- and properly seat the nail within the femur.

The proximal end of the nail is a solid cylinder with three screw holes. The screw holes are arranged in a way to allow the surgeon options in reconstruction of the fracture fragments. The two most proximal screw holes are angled at 130 degrees from the diameter of the nail, are parallel and in line with one another. These interlocking screws improve fixation of fractures in the head and neck of the femur as well as increasing stability. The third hole from the proximal end is perpendicular to the diameter of the nail and allows for reattachment of the tuberosities if necessary.

The proximal end of the nail is slotted, allowing the surgeon to orient instrumentation.

The distal portion of the nail is solid and cylindrical in shape. Distally there are two interlocking screw holes. One of the holes is round allowing for a tight fit with respect to the screw, and the other is elongated to allow some flexibility for the screw placement desired by the surgeon.

There are different sizes of cannulated endcap extensions. The extensions are used to "cap" the proximal end of the nail thereby preventing ingrowth and allowing the surgeon

greater access to the threaded end of the nail, by simply removing the endcap, if it would ever need to be removed.

There are two different screw types designed to be used with this nail. The first is the TI-cannulated cancellous screw which is a titanium cannulated screw used in the proximal portion of the nail. There are several different sizes of the TI-cannulated cancellous screw (see component listing). The other type of screw used in conjunction with this nail is the TI-pilot threaded screws. These screws are designed to have a diameter of 4mm with a 6mm diameter for the holding threads giving this screw greater strength and not allowing it to migrate during healing.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

1. Nonunion or delayed union which may lead to breakage of the implant.
2. Bending or fracture of the implant. Loosening and/or migration of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Limb shortening due to compression of the fracture or bone resorption.
5. Decrease in bone density due to compression of the fracture or bone resorption.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma.
8. Necrosis of bone.

Substantial Equivalence: In function and overall design Biomet's Holland Femoral Nail System is equivalent to most other intramedullary nails on the market.

Commercially available intramedullary femoral nails include:

Synthes Titanium Unreamed Femoral Nail (Synthes)
Alta® Femoral Nail (Howmedica)

The intramedullary (IM) nails above and the Biomet Holland Nail are similar in both their intended use and the basic concept by which they are used.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 1998

Mr. Fred McClure
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K983641
Holland Femoral Nail System
Regulatory Class: II
Product Code: HSB
Dated: October 14, 1998
Received: October 16, 1998

Dear Mr. McClure:

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.

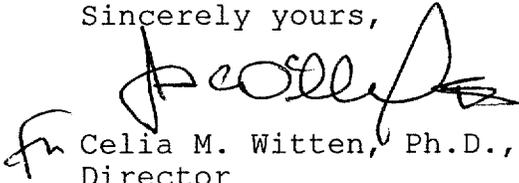
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,


fr 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 (if known) : _____

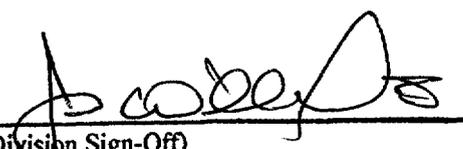
Device Name: Holland Femoral Nail System

Indications For Use: 1) fresh fractures of the femur to include; non-comminuted midshaft fractures, subtrochanteric fractures, distal third fractures, combination fractures of the shaft and neck, intertrochanteric fractures, combination intertrochanteric and subtrochanteric fractures. 2) osteotomy and reconstructive procedures following tumor resection. 3) revision procedures where other treatments or devices have failed. 4) arthrodesis.

This device is a single use implant.

Prescription Use _____
(Per 21 CFR 801.109)

X



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number 1K983641

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