

K971016

JUL 18 1997

Summary of Safety and Effectiveness Information

Product: Atlas[®] Fracture Proximal Humeral Nail

Intended Use: Fixation of fractures of the proximal humerus. The device is a single use implant.

Device Description: The Atlas Fracture Proximal Humeral Nail is a modular intramedullary rod. The proximal piece is a solid cylinder with multiple screw holes. Screw holes are placed in such a way to allow the surgeon options in reconstruction of the fracture fragments. Depending on the nature of the fracture, the humeral head, for example, may be fixed by a screw placed perpendicular to the nail, or an upward angle. If the tuberosities need to be reattached, holes placed 45 degree with respect to the holes used for head reattachment. Additionally, suture holes are provided for soft tissue reattachment.

The distal piece is a cylindrically shaped solid intramedullary stem tapered at the tip to conform to the natural humeral geometry. The stem is fluted to provide rotational stability at insertion. Longer stem lengths ($\geq 175\text{mm}$) are available with three distal screw holes, in different planes, allow additional screw placement. Holes are sized larger than the screws to allow for clearance. Distal stems with screw holes are provided with a polyethylene plug friction fit into the screw holes. These are simply pushed out by the surgeon for the holes to be used. All lengths are available without screw holes. The proximal piece and distal stems attach by means of screw threads.

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

Blood Vessel Damage	Bone Fracture	Infection
Delayed Wound Healing	Nerve Damage	Hematoma
Metal Sensitivity	Implant Fracture	Non-Union or Delayed Union
Cardiovascular Disorders		

Substantial Equivalent Devices: The Atlas Fracture Proximal Humeral Nail is substantially equivalent to other humeral nails on the market.

Altra Modular Trauma System (Howmedica)
Modular Nail (Richards)
Uniflex Humeral Nail (Biomet)
Polarus (Acumed)

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Airport Industrial Park
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Food and Drug Administration
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Rockville MD 20850

Ms. Patricia Sandborn Beres
Director, Regulatory Affairs
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

JUL 18 1997

Re: K971816
Atlas® Fracture Proximal Humeral Nail
Regulatory Class: II
Product Code: HSB
Dated: May 14, 1997
Received: May 16, 1997

Dear Ms. Beres:

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.

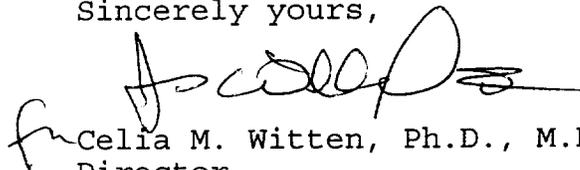
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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



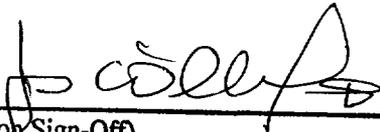
Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Atlas® Fracture Proximal Humeral Nail

Indications For Use: Fixation of fractures of the proximal humerus. The device is a single use implant.



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971816

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

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)