

APR 11 2000



CORPORATE HEADQUARTERS

## SUMMARY OF SAFETY AND EFFECTIVENESS

**Proprietary Name:** Mallory/Head Calcar Replacement with Interlocking Slots  
Bi-Metric Porous Collared Stem with Interlocking Slots

**Classification Name:** Prosthesis, hip, semi-constrained, metal/polymer, porous, uncemented (888.3558)

**Device Classification:** Class II

**Device Product Code:** 87LPH

**Indications for Use:** Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis.

**Device Description:** The Interlocking Hip Stems are metallic femoral stems with transverse screw holes in the distal portion. These devices offer a combination of total hip replacement with the benefits of an intramedullary nail. Each stem has three medial/lateral slots.

Two styles of stems are available. The first geometry is that of a Mallory/Head Calcar device. This device provides head/neck replacement to compensate for bone deficiencies in the proximal/medial portion of the femur. The second style of stem is that of Biomet's Bi-Metric device. This device has a bi-planner taper which promotes increased proximal off-loading and filling of the metaphysis. The device has a collar.

The cross-screws are available in lengths of 25mm to 60mm and 5mm diameters. Only the end of the screw is threaded so that the portion of the screw that resides inside the stem is smooth.

The femoral stems are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F-620. The cross-screws are manufactured from Ti-6Al-4V conforming to ASTM F-136.

**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:

Fracture of the component	Deformity of the joint	Bone fracture
Implant loosening/migration	Delayed wound healing	Hematoma
Blood vessel damage	Metal sensitivity	Infection
Breakdown of porous surface	Soft tissue imbalance	Dislocation
Nerve damage	Cardiovascular disorders	Excessive wear
Tissue ingrowth failure	Fracture of Screws	

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APR 11 2000

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

Re: K990830/S2  
Trade Name: Interlocking Hip Stems  
Regulatory Class: II  
Product Code: LPH  
Dated: January 14, 2000  
Received: January 18, 2000

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 control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

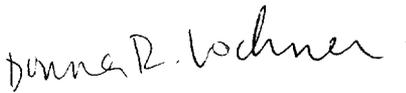
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Donna D. Lochner

 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): K990830

Device Name: Interlocking Hip Stems

**Indications For Use:**

Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Dan R. Kochner*  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K990830

Prescription Use X  
(Per 21 CFR 801.109)

OR

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