K983035

NOV 23 1998

BIOMET INC®

CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

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

Device Name: Patient Matched Flanged Acetabular Component

Classification Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis (888.3358) and Hip joint metal/polymer semi-constrained cemented prosthesis (888.3350)

Intended Use: The Patient Matched Flanged Acetabular Component is indicated for use in patients requiring reconstruction of the hip joint due to disease, deformity or trauma. The device is intended for either cemented or cementless application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints. The device is a single use implant. The device is to be used in conjunction with Biomet's RingLoc® Acetabular Liners. The device may be used in conjunction with any commercially available femoral component.

Device Description: The Patient Matched Flanged Acetabular Component is an acetabular cup designed to match the natural geometry of an individual patient. Since each Patient Matched Flanged Acetabular Component is matched to a particular patient, a specific device description is not possible.

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:

Reaction to the bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disorders	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Breakdown of the porous surface	Tissue growth failure	Nerve damage

Substantial Equivalence: The Patient Matched Flanged Acetabular Component is substantially equivalent to almost all acetabular devices on the market in overall design and intended function. Predicate devices include:

Healey™ Revision Acetabular Component
Recovery Protusio Cage
Universal® Acetabular Component
Mallory-Head® Acetabular Component

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE 219.267.6639 ■ FAX 219.267.8137 ■ E-MAIL biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 1998

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

Re: K983035
Trade Name: Patient Matched Flanged Acetabular Component
Regulatory Class: II
Product Codes: LPH and JDI
Dated: August 27, 1998
Received: August 31, 1998

Dear Ms. Beres:

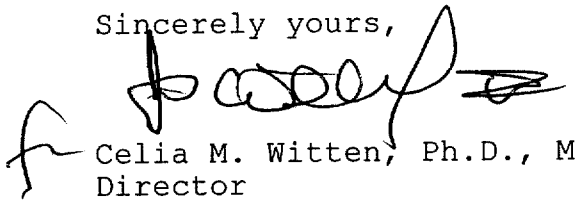
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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): k983035

Device Name: Patient Matched Flanged Acetabular Component

Indications For Use:

The Patient Matched Flanged Acetabular Component is indicated for use in patients requiring reconstruction of the hip joint due to disease, deformity or trauma. The device is intended for either cemented or cementless application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints. The device is a single use implant. The device is to be used in conjunction with Biomet's RingLoc® Acetabular Liners. The device may be used in conjunction with any commercially available femoral component.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number k983035

Prescription Use X
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)