K 030861

BIOMET

JUN 12 2003

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: HA PMI Flanged Acetabular Component

Common Name: Hip replacement acetabular prosthesis

Classification Name: Hip joint metal/polmer/metal semi-constrained, porous-coated, uncemented prosthesis (21 C.F.R. 888.3358)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: PMI Flanged Acetabular Component – 510(k) K983035

Device Description: A surgeon will request a PMI device over a standard line product in order to better fill the patient's natural anatomy. For example, a Patient Matched Flanged Acetabular Component might be requested in cases of unusual anatomy or extensive bone loss. In such cases, a hemispherical acetabular component, which only has the option of screw fixation in the socket area, may not provide stability that can be obtained through additional screw fixation in the flanges.

Since each cup is matched to a particular patient, a specific device description is unavailable.

Intended Use: The HA PMI 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 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 any commercially available femoral component.

Summary of Technologies: The HA PMI Flanged Acetabular Components are similar to or identical in materials, design, sizing and processing to the predicate device.

Non-Clinical Testing: Mechanical testing and engineering analysis has justified the modifications to this device.

Clinical Testing: None provided

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2003

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

Re: K030861
Trade/Device Name: HA PMI Flanged Acetabular Component
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: March 17, 2003
Received: March 18, 2003

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

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

Enclosure

510(k) Number (if known): K030861

Device Name: HA PMI Flanged Acetabular Component

Indications For Use:

The HA PMI 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 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 any commercially available femoral component.

(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)
Division of General, Restorative and Neurological Devices

510(k) Number K030861