FEB 7 2000

K000254

BIOMET INC

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.

Contact Person: Patricia Sandborn Beres

Trade Name: Par 5 Acetabular Component

Classification Name: Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 8883350)

Indications for Use:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of nonunion, femoral neck fractures, and throchanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
5) Revision of failed total joint construction or treatment

Device Description: The Par 5 Acetabular Component is a hemispherical metallic acetabular cup with a hook, flange and/or blade extending from the cup rim. The dome of the shell has six holes for placement of 6.5mm cancellous screws similar to a traditional acetabular component. Additionally, the shell has three counterbores for attachment of the hook and blade components and a mounting flange for attachment of the ilium flange. The shell accepts a standard Biomet Ring-loc liner.

The forked ilium flange is available in three sizes: small, medium and large and in left, right and straight configurations. Screw holes allow attachment of the flange to the bone. The flange is malleable and can be shaped by the surgeon intraoperatively to fit the shape of the patient's anatomy to provide additional support. The ilium flange is attached to the shell at the mounting flange by the component geometry and screw fasteners.

The malleable hook is placed within one of the counterbores of the shell in a position where it will reside beneath the teardrop of the ishium. The hook is formed to the patient's anatomy by the surgeon. The component is held to the shell by a screw.

The blade component is intended to enter the ishium bone in a manner similar to a screw. The curvature of the blade resembles the curvature of the ishium. This component is held to the shell by placement of the acetabular liner and secondarily, by a screw.

The ilium flange and hook are fabricated from commercially pure (CP) titanium. The cup and blade are fabricated from titanium alloy (Ti-6Al-4V) conforming to ASTM F-136. The outer surface of the shell is porous coated with titanium plasma spray.

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biomet@biomet.com

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

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

Re: K000254
Trade Name: PAR 5 Acetabluar Component
Regulatory Class: II
Product Code: JDI
Dated: January 27, 2000
Received: January 28, 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.

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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000254

Device Name: Par 5 Acetabular Component

Indications For Use:

The indications for the Par 5 Acetabular Component are as follows:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of nonunion, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
5) Revision of failed total joint construction or treatment

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000254

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)