SEP 2 2 1999

K992144

510(k) Summary

Submitted By: BioPro
17 17th Street
Port Huron, MI 48060

Contact: Cheryl Warsinske
(810) 987-7777 Fax: (810) 982-7794

Device Information:

proprietary name: BioPro Rimmed Acetabular Component
common name: Prosthesis, Hip, Semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented 87LZO
classification name: Prosthesis, Hip, Semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented 87LZO

BioPro Rimmed Acetabular component:
The rimmed acetabular component is manufactured of Titanium 6 A1-4V Eli (ASTM F136). It is available in five sizes: 54mm, 58mm, 64mm, 70mm, and 76mm. The BioPro rimmed acetabular component accommodates BioPro's 28mm and 32mm Cox Comb inserts: 28x55 (10068), 28x58 (10069), 28x65 (10071), 28x69 (10074), 28x75 (11227), 32x55 (10077), 32x58 (10078), 32x65 (10081), 32x69 (10083), and 32x75 (10084).

Substantial Equivalence:

The BioPro Rimmed Acetabular Components are substantially equivalent to the Biomet Healey Flanged Revision Acetabular Shells. See Appendix C for more information on the Biomet Healey Flanged Revision Acetabular Shell. Both styles are manufactured from Titanium, are porous coated, and are to be used with a polyethylene insert. Both the BioPro Rimmed and Biomet acetabular components are designed to be fastened to the acetabulum with the use of bone cement and/or titanium bone screws and have a shape and hole configuration that allows the cup to be positioned in the pelvis. The BioPro shell does not have multiple screw holes located within the shell, while the Biomet shell has multiple screw holes placed concentrically within the shell. Both shells also possess a rimmed flange. The BioPro shell has two flanges with one hole in each and one flange with six holes in it, while the Biomet shell has one flange with three holes in it. Although both styles are to be used with a femoral ball, the ball sizes to accommodate the components differ. The BioPro acetabular components must be used with either a 28mm or 32mm femoral ball, while the Biomet acetabular component must be used with either a 22mm, 26mm, 28mm, or 32mm femoral ball. The size of shell also differs. The BioPro shell is offered in 54mm, 58mm, 64mm, 70mm, and 76mm, while the Biomet shell is offered in 48mm to 70mm in 2 mm increments.

Although there are minor differences between the BioPro acetabular component and the Biomet acetabular component, they are substantially equivalent in form and function. Both systems are indicated for treatment for congenital acetabular cavity defects, bone deficiency from osteolysis, for revision surgery, rheumatoid arthritis with severe hip pain and limited joint motion, avascular necrosis, and traumatic arthritis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1999

Cheryl L. Warsinske, M.S.
Director of Engineering
BioPro, Inc.
17 Seventeenth Street
Port Huron, Michigan 48060

Re: K992144
Trade Name: BioPro Rimmed Acetabular Component
Regulatory Class: II
Product Code: LZO and JDI
Dated: June 23, 1999
Received: June 24, 1999

Dear Ms. Warsinske:

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 at (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

510K) Number (if known): K992144

Device Name: BioPro Rimmed Acetabular Component

Indications For Use:

1. Osteoarthritis
2. Rheumatoid arthritis with severe hip pain and limited joint motion.
3. Avascular necrosis
4. Traumatic arthritis
5. Acetabular cavity deformities caused by congenital problems.
6. Revisional surgery after one or more total hip operations.
7. Fixation with bone cement and/or cancellous bone screws.

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992144

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use_____

(Optional Format 1-2-96)