4/29/99

K990821

510 (k) Summary

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

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

Device Information:

Proprietary name: Providence Cup System

Common name: Prosthesis, Hip, Semi-constrained, metal/ceramic/polymer, cemented or non-porous uncemented

Classification name: Prosthesis, Hip, Semi-constrained, metal/ceramic/polymer, cemented or non-porous uncemented

Acetabular Cup
The Providence acetabular shell is manufactured from 6-4 Eli Titanium. It is porous coated and contains screw holes to allow for additional fixation. The acetabular component houses 28mm and 32mm ID inserts that are either neutral or lipped. It is available in eight sizes: 46mm, 48mm, 50mm, 52mm, 54mm, 56mm, 58mm, and 60mm.

Acetabular Insert
The Providence acetabular insert is manufactured from UHMWPE. It is designed to snap-fit into the acetabular cup. The acetabular cup will accept 28mm and 32mm heads. It is available in both a neutral and hooded variety. The insert is available in sizes ranging from 46mm to 60mm.

Screw Plug
The Providence screw plug is manufactured from 6-4 Eli Titanium. It is used to plug the threaded impaction hole in the acetabular shell.

Substantial Equivalence:
The Providence Cup System is substantially equivalent to the Horizon Cup System (510k # K962769). Both cups are low profile cups and both house the same acetabular insert. The OD of both cups is porous coated. The Providence shell is also equivalent to the Interseal shell from Wright Medical Technology. The outer geometry of the two cups is very similar.

The Horizon cup is manufactured from cobalt chrome and the Providence cup is manufactured from titanium. The Interseal cup is cobalt chrome.

The Horizon cup contains three external pegs, which aid in fixation, while the Providence cup contains screw holes to accept screws for fixation. The Providence cup contains a through impaction hole to accept an impaction tool. The Horizon cup contains a blind impaction hole. A screwplug is provided to plug the impaction hole in the Providence cup. The Interseal cup also contains an impaction hole in the dome and can be used with a screwplug.

Although there are minor differences between the Horizon cup and the Providence cup, they are substantially equivalent in form and function. All three systems are indicated for treatment of osteoarthritis, rheumatoid arthritis, avascular necrosis, and traumatic arthritis. Contraindications include: excessive bone loss, septic arthritis, periarticular osteomyelitis, and local or systemic infection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1999

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

Re: K990821
Trade Name: Providence Cup System
Regulatory Class: II
Product Codes: JDI and LZO
Dated: March 5, 1999
Received: March 11, 1999

Dear Ms. Warsinske:

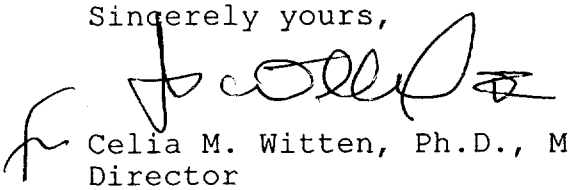
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

K990821

510k Number (if known):

Device Name: The Providence Cup System

Indications for Use:

A) Osteoarthritis
B) Rheumatoid arthritis with severe hip pain and limited joint motion
C) Avascular necrosis
D) Traumatic arthritis
E) To be used in conjunction with a Biopro femoral stem and a 28mm or 32mm Biopro ceramic or cobalt chrome head.

(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 K990

Prescription Use---X--- OR Over The Counter Use------
(Per 21 CFR 801.109) (Optional Format 1-2-96)