K973163

510(k) Summary

NOV 21 1997

Proprietary Name: Acetabular Shells with Mesh Ingrowth Surface

Common Name: Modular Acetabular Component

Classification Name and Reference: 21 CFR 888.3358
Hip Joint Metal/Polymer/Metal semi-constrained porous coated uncemented prosthesis.

Proposed Regulatory Class: Class II

Device Product Code: JDI

For information contact: Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7875
Fax: (201) 507-6870
Date Summary Prepared: 8-22-97

The Acetabular Shells with Mesh Ingrowth surface are a series of Vitallium® acetabular components intended for the primary reconstruction of the acetabulum during total hip arthroplasty.

These components are designed with a mesh ingrowth surface that is integrally cast in to the shell substrate. The shells are available in a range of outer diameters to accommodate various anatomical requirements. These shells are available in four styles; a solid back, a solid back with visualization hole, a cluster shell with screw holes, and a shell that is pre-assembled with the plastic insert.

The substantial equivalence of these devices is based on an equivalence in intended use, design, materials, manufacturing methods, and indications and contraindications to Howmedica's Vitalock® Solid Back Shells(K930223, K935731, K952397), Vitalock® Cluster Cup(K933102), and Zimmer's Trilogy™ Acetabular Cup(K954698).

Mechanical as well as Biological testing was presented to demonstrate the equivalence of the cast mesh surface to that of a sintered beaded porous coating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

NOV 21 1997

Re: K973163
Trade Name: Acetabular Shells with Mesh Ingrowth Surface
Regulatory Class: II
Product Code: LPH
Dated: August 22, 1997
Received: August 25, 1997

Dear Mr. Maas:

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

Indications for Use

510(k) Number (if known):

Device Name: Acetabular Shells with Mesh Ingrowth Surface

Indications for Use:

The Acetabular Shells with Mesh Ingrowth Surface are intended to be used for uncemented, primary reconstruction of the acetabular portion of the hip joint during total hip arthroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973163