K981201

MAY 29 1998

510(k) Summary

Proprietary Name: Osteolock™™ Acetabular Cup

Common Name: Acetabular Shell

Classification Name and Reference: CFR 888.3353
This device is a component of a hip joint, semi-constrained, metal/ceramic/polymer, cemented or non-porous uncemented prosthesis.

Proposed Regulatory Class: Class II

Device Product Code: OR(87)LZO

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: 4/17/98

The Osteolock™™ Acetabular Cup has been previously cleared (510(k) 903362) for cemented use in the replacement of the bearing portion of the acetabulum in primary or revision total hip arthroplasty. This submission adds the uncemented use of this device as an additional indication. There are no changes to the design, manufacturing methods or operational principles of the device.

The titanium plasma spray coating on the outer aspect of the shell provides a roughened surface texture. This plasma spray coating is not a porous coating and, as such, this cup is intended to be press fit into the acetabulum.

Assembly/disassembly testing of the liner from the shell as well as the characterization of the plasma spray coating was presented in the previous submission.

The substantial equivalence of the Osteolock™™ Cup is based on an equivalence in intended use, materials, design, operational principles, and relative indications and contraindications to the currently marketed Osteolock™™ Acetabular Cup (K903362).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1998

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

Re: K981201
Trade Name: Osteolock™ Acetabular Cup
Regulatory Class: II
Product Codes: LZO and LWJ
Dated: April 2, 1998
Received: April 2, 1998

Dear Mr. Maas:

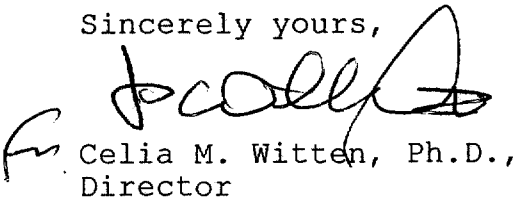
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K981201

Device Name: Osteolock™ Acetabular Cup

Indications for Use:

The Osteolock™ Acetabular Cup is intended to be used to replace the bearing portion of the acetabulum in primary or revision total hip arthroplasty. These components are designed to be press fit into the acetabulum. They do not achieve fixation by biological ingrowth.

(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 K981201