

K971854

**510(k) Summary**

JUL 30 1997

Proprietary Name: Osteolock™ Acetabular Shell System

Common Name: Acetabular Shell without Screw Holes

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: 5/19/97

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

The Osteolock™ Acetabular Shells are available in outer diameters from 38-80mm in two millimeter increments. The shells are available in four styles: one with a north pole visualization hole, one without a north pole hole, one with screw holes, and one that is pre-assembled with the plastic inserts. The inner aspect of the shell has scalloped depressions which form part of the locking mechanism for the acetabular insert. All shells are manufactured from Titanium alloy conforming to ASTM-F136.

There is a Titanium plasma spray coating on the outer aspect of the shell to provide 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.

There is an apical hole plug which may be used in the design with a north pole hole. This apical hole plug is press fit into the north pole hole after the acetabular cup has been seated. The apical hole plug is designed to close the north pole hole to reduce the possibility of polyethylene debris egress from this opening.

Assembly/disassembly testing of the liner from the shell was presented, along with characterization of the plasma spray coating.

The substantial equivalence of the Osteolock™ Shells is based on an equivalence in intended use, materials, design, operational principles, and relative indications and contraindications to Howmedica's Osteolock™ Acetabular Cup with Screw Holes (K903362); Vitalock® Solid Back Shells (K952397); Vitalock® Spiked Acetabular Shell (K953664); Osteolock™ CL Femoral Stem (K944592); and Osteonics' Arc Deposition Hip Components.



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

JUL 30 1997

Re: K971854  
Osteolock™ Acetabular Shell System  
Regulatory Class: II  
Product Code: LPH  
Dated: May 19, 1997  
Received: May 20, 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.

Under Section 522(a) of the act, manufacturers of certain types of devices identified by the Act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under Section 522(a)(1)(C) the device cleared for marketing by this letter as requiring postmarket surveillance. The rationale for this decision is contained in the enclosed attachment.

Within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you are required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is attached.

Submit five (5) copies to:

Center for Devices and Radiological Health  
Postmarket Surveillance Studies Document Center  
Room 3083 (HFZ-544)  
1350 Piccard Drive  
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. You should not begin your postmarket surveillance study of this device until the protocol has been approved. Data generated under an unapproved protocol may not satisfy your obligation under section 522. Please note that you must continue to collect and report data needed to maintain compliance with Medical Device Reporting regulations (21 CFR 803).

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete an FDA approved postmarket surveillance study consistent with the protocol will be considered violations of section 522. In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the Act (21 U.S.C. 331 (q)(1)(C)). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

If you have questions concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

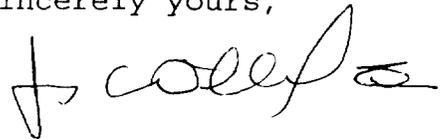
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

Page 4 - Mr. Frank Maas

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,

  
f. Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K971854

Device Name: Osteolock™ Acetabular Shell System

Indications for Use:

The Osteolock™ Acetabular Shells are 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    
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

**(Division Sign-Off)**  
**Division of General Restorative Devices**

510(k) Number \_\_\_\_\_

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