

AUG 31 1998

K98 2248  
510(k) Summary

Proprietary Name: Howmedica® Asymmetric Stem, Vitalock® Cluster & Spiked Shells, and Acetabular Shells with Mesh Ingrowth Surface with Peri-Apatite™ Coating

Common Name: Porous Coated Hip Prosthesis and Acetabular Shell with Precipitated Calcium Phosphate Coating

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: LPH/MEH

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: 6-26-98

The Howmedica® Asymmetric Stem, Vitalock® Cluster & Spiked Shells, and Acetabular Shells with Mesh Ingrowth Surface with Peri-Apatite™ Coating are intended to be used in the primary uncemented reconstruction of the proximal femur and acetabulum. These devices are identical to the previously cleared Asymmetric Stem, Vitalock® Cluster Shell, Vitalock® Spiked Shell and Mesh Shells, except for the presence of a thin layer of hydroxyapatite coating applied to the porous coated surface.

The Peri-Apatite™ coating is the same coating previously characterized and cleared in 510(k) K971206.

The substantial equivalence of these devices is based on an equivalence in intended use, materials, design, and relative indications and contraindications to Howmedica's Meridian® ST Stem and Vitalock® Solid Back Shell with Peri-Apatite™ Coating (K971206), Asymmetric Stem (K955871), Vitalock® Cluster Shell (K933102), Vitalock® Spiked Shell (K953664), and Mesh Ingrowth Shells (K973163).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 31 1998

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

Re: K982248  
Howmedica® Asymmetric Stem, Vitalock® Cluster and Spiked  
Shells, and Acetabular Shells with Mesh Ingrowth  
Surface with Peri-Apatite™ Coating  
Regulatory Class: II  
Product Codes: MEH and LPH  
Dated: June 26, 1998  
Received: June 26, 1998

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for "enhanced clinical or radiographic performance, enhanced biological fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional porous coated hip prosthesis (i.e., biological fixation only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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. 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.

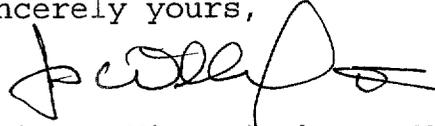
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

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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,



*fr* 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): K982248

Device Name: Howmedica® Asymmetric Stem, Vitalock® Cluster & Spiked Shells, and Acetabular Shells with Mesh Ingrowth Surface with Peri-Apatite™ Coating

Indications for Use:

The Howmedica® Asymmetric Stem, Vitalock® Cluster & Spiked Shells, and Mesh Ingrowth Shells with Peri-Apatite™ Coating are intended to be used in the primary uncemented reconstruction of the proximal femur and acetabulum, respectively.

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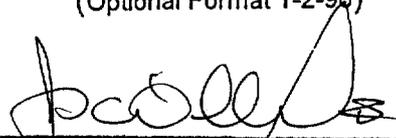
\_\_\_\_\_ Concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division) Sign-Off  
Division of General Restorative Devices  
510(k) Number K982248