K971206

510(k) Summary

FEB 11 1998

Device: Meridian® ST Femoral Stem and Vitalock® Solid Back Shell with Peri-Apatite™ Coating

Classification Name and Reference:

Hip Joint Metal/Polymer/Metal Semi-Constrained Porous Coated Uncemented Prosthesis 21 CFR 888.3358

Proposed Regulatory Class: Class II (reclassified 1-8-93)

For information contact: Margaret F. Crowe
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7431
Fax: (201) 507-6870

The Meridian® ST Femoral Stem and Vitalock® Solid Back Shell with

Peri-Apatite™ Coating are intended to be used in the primary uncemented reconstruction of the proximal femur and acetabulum damaged as a result of non-inflammatory joint disease, avascular necrosis or trauma. These devices are identical to the Meridian® ST femoral stem and Vitalock® Solid Back shell previously released under K940307, K930223, and K952397 respectively, except for the presence of a thin layer of hydroxyapatite coating applied to the porous coated surface.

The Meridian™ ST Femoral Stem and Vitalock® Solid Backed Acetabular Shell with Peri-Apatite™ Coating are equivalent to other legally marketed devices in commercial distribution. These products are listed below:

1. Meridian™ ST Femoral Stem - Howmedica
2. Vitalock® Solid Backed Acetabular Shell - Howmedica
3. Osteolock™ HA Femoral Stem - Howmedica

This equivalence is based upon similarities in intended use, material, design, and operational principles to the legally marketed devices.

Testing to characterize the Peri-Apatite™ coating was presented, along with the results of an animal study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Margaret F. Crowe
Group Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

FEB 11 1998

Re: K971206
Meridan™ ST Femoral Stem and Vitalock® Solid Back Shell with Peri-Apatite Coating
Regulatory Class: II
Product Codes: LPH and MEH
Dated: November 12, 1997
Received: November 13, 1997

Dear Ms. Crowe:

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). 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 "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, 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 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,

for 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

Device Name: Meridian™ ST Femoral Stem and Vitalock® Solid Back Acetabular Shell with Peri-Apatite™ Coating

Indications for Use:

The Meridian™ ST Femoral Stem and Vitalock® Solid Back Acetabular Shell with Peri-Apatite™ Coating are intended to be used in the primary uncemented reconstruction of the proximal femur and acetabulum damaged as a result of non-inflammatory joint disease, avascular necrosis or trauma.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Restorative Devices
510(k) Number K971206