K97 2X93

NOV - 3 1997

510(k) Summary

Proprietary Name: Partnership Revision Femoral Components

Common Name: Hip Prosthesis

Classification Name and Reference: 21 CFR 888.3353
Hip Joint Metal/Ceramic/Polymer semi-constrained cemented or nonporous uncemented prosthesis.

Proposed Regulatory Class: Class II

Device Product Code: 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: 8-1-97

The Partnership Revision Femoral Components consist of a family of Titanium femoral stems with Titanium plasma spray coating. The stems are intended to be used with Howmedica V40™ femoral heads, Howmedica Unipolar and Bipolar components, and Howmedica acetabular components in primary and revision total hip arthroplasty. These femoral stems are designed to be press fit into the proximal femur. They do not achieve fixation by biological ingrowth.

These femoral components will be made available in two substrate alloys: 1) Ti-6Al-4V, which meets the requirements of ASTM specification F 136; or 2) TMZF alloy (Ti-11.5 Mo-6Zr-2 Fe). The TMZF alloy is the subject of draft ASTM specification F 1813. The Titanium plasma spray coating is CP titanium, which conforms to ASTM specification F 1580.

The substantial equivalence of the Partnership Revision Femoral stems is based on an equivalence in intended use, materials, design, and relative indications and contraindications to Howmedica's Meridian® Femoral Stem (K940307), Osteolock™ CL Femoral Stem, TMZF (K944592), Osteolock™ CL Femoral Stem, Ti-6Al-4V (K941141), Osteonics' Restoration Monolithic II Slotted Hip Stems (K951671), and Zimmer's Multilock Hip Prosthesis (K921308).

Testing has demonstrated that the fatigue load carrying capacity of the Partnership Revision Femoral stems exceeds the minimum ISO load requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1997

Mr. Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, New Jersey 07070

Re: K972893
Partnership Revision Femoral Components
Regulatory Class: 2
Product Codes: LZO and LPH
Dated: August 4, 1997
Received: August 5, 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 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 at (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

Enclosures

RATIONALE FOR POSTMARKET SURVEILLANCE REQUIREMENTS FOR PLASMA SPRAYED POROUS COATED HIP SYSTEMS

The Center for Devices and Radiological Health (CDRH) is requiring that manufacturers of plasma sprayed porous coated hip prostheses cleared through the 510(k) process whose submissions lack nine year clinical data demonstrating the long-term safety and effectiveness of the device, conduct postmarket surveillance, pursuant to section 522(a)(1)(C) of the Food, Drug, and Cosmetic Act (Act). This surveillance is required for the reasons discussed below.

Long-term (i.e., nine years and greater) clinical investigations of the mechanical strength of sintered porous coatings made from cobalt-chrome beads or titanium fiber mesh have provided a reasonable assurance of the safety and effectiveness of hip prostheses with these coatings, (See 58 **FR** 3227, Jan. 8, 1993). In bench testing, plasma sprayed porous coatings have demonstrated lower mechanical strength and, in particular, lower resistance to abrasion than that ynoted for sintered cobalt-chrome bead or sintered titanium fiber mesh coatings. Thus, while short-term (i.e., less than four years) clinical data uncovers no difference in the clinical failure rates between plasma spray porous coated hip prostheses and hip systems with sintered porous coatings, because of the lack of long-term clinical safety and effectiveness information, CDRH believes that hips covered by plasma sprayed porous coatings should be monitored to insure that they are not prematurely failing due to metal debris, coating spalling, or coating delamination. These concerns, if realized, could result in significant incapacitation and require revision surgery.

The Food and Drug Administration (FDA) will determine if your protocol will result in the collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device. We anticipate that an acceptable protocol will provide an actuarial survivorship analysis over a nine year period by monitoring what proportion of hips are revised in a representative sample of several hundred patients in whom the device was implanted, without bone cement, for rehabilitation of a hip damaged by noninflammatory degenerative joint disease.

Stratification of the data may be necessary according to revision of the acetabular component, the femoral component, or both components. It is appropriate to further judge clinical success by obtaining patient self-assessment of how well the hip prosthesis is functioning. You will also need to collect data on patient deaths, losses to follow-up, and baseline variables which could potentially confound the survivorship data (e.g., device configuration of stem and cup models, diagnosis, and patient condition prior to initial implantation as judged by Harris Hip Score). Such data should function as an early warning system for late occurring effectiveness and safety problems.

Indications for Use

510(k) Number (if known):

Device Name: Partnership Revision Femoral Stems

Indications for Use:

The Partnership Revision Femoral Stems consist of a family of Titanium femoral stems with Titanium plasma spray coating that are intended to be used with Howmedica V40™ femoral heads, Howmedica Unipolar and Bipolar components, and Howmedica acetabular components in primary and revision total hip arthroplasty. These femoral stems are designed to be press fit into the proximal femur. 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 K972893