

# 510(k) Summary for the 2 Piece Modular Hip Stem

K013106 P1/2

APR 03 2002

**Proprietary Name:** 2 Piece Modular Hip Stem

**Common Name:** Femoral 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:** OR(87) LZO

**For Information contact:** Jennifer A. Daudelin  
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Howmedica Osteonics Corp.  
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**Date Summary Prepared:** January 24, 2002

The 2 Piece Modular Hip Stem is a modular system comprised of a proximal body, distal stem, and locking bolt. These three individual components utilizing a modular junction are assembled by the surgeon in the operating room or in situ to allow independent sizing of the proximal body and distal stem. This system is designed so that all proximal components will be able to mate with all distal components, thus affording optimal flexibility.

This system is intended to be used for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. The stems are intended to be used with Howmedica Osteonics femoral heads, unipolar and bipolar components, and acetabular components. These femoral stems are designed to be press fit into the proximal femur.

The 2 Piece Modular Hip Stem components will be fabricated from Titanium (Ti6Al-4V) Alloy. The Cone, Broached, and Milled body components as well as the Porous Stems will be offered with plasma spray or plasma spray and hydroxylapatite coatings.

## 510(k) Summary for the 2 Piece Modular Hip Stem

K013106 P2/2

The fatigue strength of the proximal and distal regions of the bodies and stems was verified using finite element techniques. For the proximal body strength analyses, testing consistent with the applicable ISO standards for neck and stem strength was conducted. The effect of taper length on the stresses in the taper region was investigated using finite element techniques. Further physical testing of the taper was undertaken to confirm strength of the junction in torsion. Additionally, the application of the PureFix® HA coating has no effect on the fatigue strength of the shot peened and plasma sprayed coating on the Ti-6Al-4V ELI Alloy.

The substantial equivalence of the 2 Piece Modular Stem is based upon equivalence in intended use, materials, design, and operational principles to the following Howmedica Osteonics devices: Type 3 Femoral Components (K983404); Partnership Revision Femoral Component (K972893); Meridian Titanium Femoral Stems (K972228); and the Citation TMZF HA Femoral Stem (K993768).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**APR 03 2002**

Jennifer A. Daudelin  
Regulatory Affairs  
Howmedica Osteonics Corp.  
59 Route 17  
Allendale, New Jersey 07401-1677

Re: K013106

Trade/Device Name: 2-Piece Modular Hip Stem

Regulation Number: 21 CFR §888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or porous uncemented prosthesis

Regulatory Class: Class II

Product Code: LZO

Dated: January 24, 2002

Received: January 25, 2002

Dear Ms. Daudelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

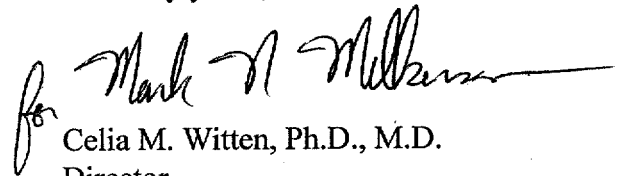
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K013106

Device Name: 2 Piece Modular Hip Stem

Indications for Use:

The 2 Piece Modular Revision Stem Components are intended to be used for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. The stems are intended to be used with Howmedica Osteonics femoral heads, unipolar and bipolar components, and acetabular components. These femoral stems are designed to be press fit into the proximal femur.

(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)

for Mark A. Millerson  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

51(k) Number K013106