K992025

AUG 13 1999

510(k) Summary

Proprietary Name:	Precision® Osteolock Femoral Stems with Pure-Fix™ HA Coating
Common Name:	Press-Fit Titanium Femoral Stem
Classification Name and Reference:	Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate
Proposed Regulatory Class:	Class II
Device Product Code:	MEH
For information contact:	Marybeth Naughton Regulatory Affairs Howmedica Osteonics Corp. 59 Route 17 South Allendale, New Jersey 07401 Telephone: (201) 934-4376 Fax: (201) 934-4368 Date Summary Prepared: 5-21-99

The purpose of this premarket notification is to describe a modification to the Precision® Osteolock Femoral Stems with Hydroxyapatite Coating (previously determined substantially equivalent via 510(k) K912395). It is the intention of Howmedica Osteonics to change the hydroxyapatite coating on these femoral stems from the Low Pressure Plasma Spray (LPPS) HA coating described in K912395 to Howmedica Osteonics Pure-Fix™ HA coating. The Pure-Fix™ HA coating was originally determined substantially equivalent on the Osteonics® Omnifit® EPF Femoral Prosthesis in premarket notification K896047. This coating has been cleared for marketing on several other Osteonics® hip prostheses.

There is no change in intended use for the Precision® Osteolock Femoral Component with Pure-Fix™ HA Coating. This stem is intended to be used for primary or secondary reconstruction of the head and neck of the femur when sufficient, good quality bone stock is present. Use of this device is indicated for reconstruction of painful and/or severely disabled hip joints resulting from osteoarthritis, rheumatiod arthritis, post traumatic arthritis, avascular necrosis, subcaptital fracture, or in revision of a failed femoral prosthesis.

This femoral stem is intended to be used with Howmedica Osteonics femoral heads with a 2° 52' taper. The femoral stem can be used with Howmedica Osteonics bipolar or unipolar devices as an endoprosthesis, or can articulate with a Howmedica Osteonics acetabular cup prosthesis in total hip arthroplasty procedures.

The Precision® Osteolock Femoral Component with Pure-Fix™ HA Coating is designed to be used in a simple cementless press-fit mode.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Ms. Marybeth Naughton
Regulatory Affairs
Howmedica Osteonics, Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K992025
Trade Name: Precision® Osteolock Femoral Component with Pure-Fix™ HA Coating
Regulatory Class: II
Product Code: MEH
Dated: June 15, 1999
Received: June 16, 1999

Dear Ms. Naughton:

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 control provisions of the Act. The general control 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.

This letter will allow you to begin marketing your device as described in your 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 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

Enclosure

Indications for Use

510(k) Number (if known): K992025

Device Name: Precision® Osteolock Femoral Stems with Pure-Fix™ HA Coating

Indications for Use:

This stem is intended to be used for primary or secondary reconstruction of the head and neck of the femur when sufficient, good quality bone stock is present. Use of this device is indicated for reconstruction of painful and/or severely disabled hip joints resulting from osteoarthritis, rheumatiod arthritis, post traumatic arthritis, avascular necrosis, subcaptital fracture, or in revision of a failed femoral prosthesis.

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(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 K992025