

DEC 22 1998

510(k) Summary

L983404

Proprietary Name: Type 3 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: 9-25-98

The Type 3 Femoral Components are a series of Titanium femoral stems intended to be used for primary or revision total hip arthroplasty, specifically in the presence of severe proximal bone loss. The stems are intended to be used with Howmedica V40™ femoral heads, Howmedica Unipolar and Bipolar components, and Howmedica acetabular components. These stems are modular, with varying proximal body and distal stem sizes to accommodate various anatomical requirements. These femoral stems are designed to be press fit into the proximal femur.

These femoral components are manufactured from Titanium alloy, Ti-6Al-4V, which conforms to the requirements of ASTM specification F 136.

The substantial equivalence of these Femoral components is based on an equivalence in intended use, materials, design, and relative indications and contraindications to Howmedica's Partnership™ Revision Femoral Components (K972893) and Modular Replacement System (K954559), Intermedics Orthopedics' Wagner Revision Stem (K960588) and Link's MP Reconstruction Hip System.

Testing has demonstrated that the fatigue load carrying capacity of the Type 3 Femoral stems exceeds the minimum ISO load requirements.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Medical Technology Group
359 Vertans Boulevard
Rutherford, New Jersey 07070-2584

Re: K983404
Trade Name: Type 3 Femoral Components
Regulatory Class: II
Product Codes: LZO, JDI, LWJ
Dated: September 25, 1998
Received: September 28, 1998

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.

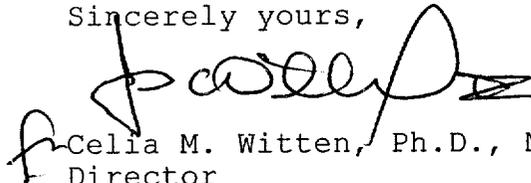
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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): K983404

Device Name: Type 3 Femoral Components

Indications for Use:

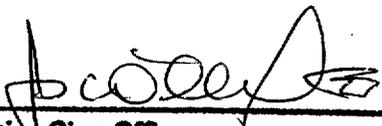
The Type 3 Femoral Components are intended to be used in primary or revision total hip arthroplasty, specifically in the presence of severe proximal bone loss. These stems are intended to be used with Howmedica V40™ femoral heads, Howmedica Unipolar and Bipolar components, and Howmedica acetabular components. 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 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 K983404