DEC 23 1997

K974054

510(k) Summary

Proprietary Name: Distal Centralizer, Exeter II Hip System

Common Name: Centralizer, Hip Stem

Classification Name and Reference: 21 CFR 888.3350
Prosthesis, Hip, Semi-Constrained, Metal/Polymer

Proposed Regulatory Class: Class II

Device Product Code: JDI

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: 10-24-97

The Exeter II Distal Centralizer is a molded acrylic device that is fitted to the distal portion of a hip stem and used to centralize the stem within the femoral canal.

The centralizer's design consists of three wing-like projections that extend outwards from the base of the centralizer. These projections contact the walls of the femoral canal, centralizing the hip stem within the canal.

The substantial equivalence of the centralizer is based on an equivalence in intended use, design, materials, operational principles, and relative indications and contraindications to Howmedica's currently marketed centralizers. These include the Definition Hip System centralizer (K 936127), and the currently marketed Exeter II Distal Centralizer (K 891445).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1997

Mr. Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K974054
Trade Name: Distal Centralizer, Exeter II Hip System
Regulatory Class: II
Product Code: JDI
Dated: October 24, 1997
Received: October 27, 1997

Dear Mr. Maas:

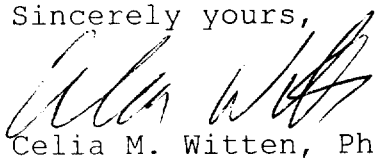
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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

K974054

# Indications for Use

510(k) Number (if known): K974054

Device Name: Distal Centralizer, Exeter II Stem

Indications for Use:

The Exeter II Distal Centralizer is intended to be used to centralize the femoral stem within the intramedullary canal. The Distal Centralizer is intended to be used with bone cement.

(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 K974054