

JUN 2 1998

510(k) Summary

K98 0 843

Proprietary Name: Intramedullary Bone Plug, Exeter Hip System

Common Name: Cement Restrictor

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

Proposed Regulatory Class: Class II

Device Product Code: LZN, **SDI**

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: 3-3-98

The Exeter Intramedullary Bone Plug is a molded acrylic device that is designed to be placed in the femoral canal prior to the insertion of a femoral stem. The bone plug restricts the migration of bone cement down the femoral canal and permits cement pressurization within the canal.

The Exeter Bone Plug described in this submission is the same design as the currently marketed device. The Bone Plug is a cone shaped device available in a range of diameters to accommodate various anatomical requirements. The distal portion of the plug is designed with circumferential ridges that create an interference fit between the plug and the femoral canal. Slots are cut into the ridge portion of the bone plug to allow the plug to compress slightly during insertion down the canal. The body of the plug contains a threaded portion for use with an insertion instrument.

The substantial equivalence of the Exeter Bone Plug is based on an equivalence in intended use, design, materials, operational principles, and relative indications and contraindications to the Howmedica's polyethylene Exeter Bone Plug, (K933077) and Exeter II Distal Centralizer (K974054).



JUN 2 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Margaret F. Crowe  
Group, Regulatory Affairs Manager  
Howmedica Inc.  
Pfizer Hospital Products Group  
359 Veterans Boulevard  
Rutherford, New Jersey 07070-2584

Re: K980843  
Trade Name: Exeter Intramedullary Bone Plug  
Regulatory Class: II  
Product Codes: JDI and LZN  
Dated: March 3, 1998  
Received: March 4, 1998

Dear Ms. Crowe:

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.

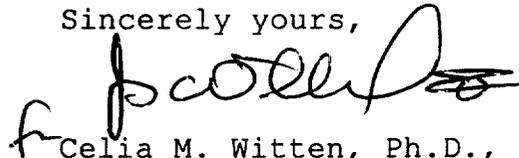
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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): **K980843**

Device Name: Exeter Intramedullary Bone Plug

Indications for Use:

The Exeter II Intramedullary Bone Plug is intended to be used to restrict the migration of bone cement down the femoral canal and permit cement pressurization during total hip arthroplasty. The Exeter Intramedullary Bone Plug is intended to be used with bone cement.

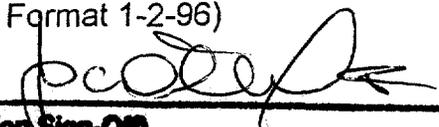
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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR  
(Per 21 CFR 801.109)

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General Restorative Devices  
510(k) Number \_\_\_\_\_

**K980843**