

JUL 13 1998

510(k) Summary

**Device: Howmedica® Modular Replacement System - Distal Femoral/Proximal Tibial Segments**

The Howmedica® Modular Replacement System - Distal Femoral/Proximal Tibial Segments are presently cleared for use with bone cement in Oncology patients where radical resection and replacement of the distal femur/proximal tibia is required (reference premarket notification K952970). Howmedica seeks clearance to expand this indication to include use with bone cement in limb salvage procedures where radical resection and replacement of the distal femur/proximal tibia is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous knee arthroplasties, and/or Oncology indications. All of these surgical interventions have in common the need for radical resection of the distal femur/proximal tibia, and the need for a prosthetic replacement. This device achieves fixation by the use of bone cement.

A comparison to other legally marketed products was made, and testing of the modular tapers was presented.

For information contact:

Margaret F. Crowe  
Manager, Regulatory Affairs  
Howmedica Inc.  
359 Veterans Boulevard  
Rutherford, NJ 07070  
(201) 507-7431  
Fax: (201) 507-6870



JUL 13 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: K972401  
Howmedica® Modular Replacement System - Distal  
Femoral/Proximal Tibial Segments  
Regulatory Class: II  
Product Code: KRO  
Dated: May 13, 1998  
Received: May 14, 1998

Dear Ms. Crowe:

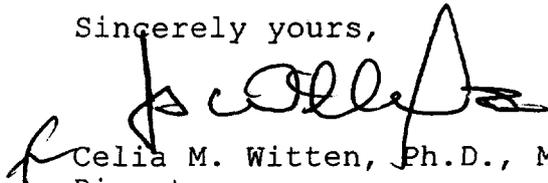
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Indications for Use

510(k) Number (if known):

Device Name: Howmedica® Modular Replacement System - Distal Femoral/Proximal Tibial Segments

Indications for Use:

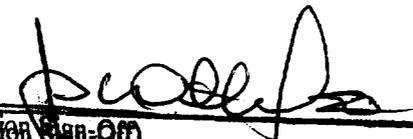
The Howmedica® Modular Replacement System - Distal Femoral/Proximal Tibial Segments are presently cleared for use with bone cement in Oncology patients where radical resection and replacement of the distal femur is required (reference premarket notification K952970). Howmedica seeks clearance to expand this indication to include use with bone cement in limb salvage procedures where radical resection and replacement of the distal femur/proximal tibia is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous knee arthroplasties, and/or Oncology indications. All of these surgical interventions have in common the need for radical resection of the distal femur/proximal tibia, and the need for a prosthetic replacement. This device achieves fixation by the use of 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  OR Over-The-Counter Use   
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

  
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(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K972401  
\_\_\_\_\_  
Restorative Devices  
510(k) Number \_\_\_\_\_