

MAY 22 1998

510(k) Summary

K980713

Device: Interax® Femoral and Tibial Plugs - Alternate Material

The Interax® femoral component and tibial baseplate previously cleared in K973121 are made available with a PMMA plug inserted onto their central stems. The purpose of this plug is to occlude the internal threaded portion of the central stem of the femoral component, and the internal taper surface of the tibial component. The PMMA plug can also be removed to allow the optional use of stem extensions. The current femoral and tibial plugs are fabricated from pellitized PMMA (Simplex P). The new femoral and tibial plugs will be made from a acrylic resin which is supplied by Rohm & Haas.

There is no change in the intended use of the femoral and tibial components of the Interax® Total Knee System - The Interax® Total Knee System is intended to be used in cemented primary and/or revision total knee arthroplasty procedures in patients who require total knee replacement as a result of non-inflammatory joint disease and all of its variants, inflammatory joint disease, trauma, or failed previous prosthesis. The Interax® system is intended to accommodate the posterior cruciate ligament if it is intact. The collateral ligaments should be intact, or reparable, or there must be adequate capsular support to provide medio-lateral stability. The Interax® Total Knee System is intended to be implanted using bone cement.

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



MAY 22 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: K980713
Femoral and Tibial Plugs of Interax® Total Knee System
Regulatory Class: II
Product Code: JWH
Dated: February 23, 1998
Received: February 24, 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.

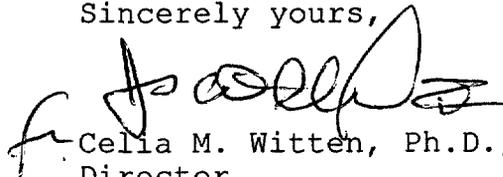
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Margaret F. Crowe

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: Interax® Femoral and Tibial Plugs - Alternate material

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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)

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number

K980723

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)