K984207

FEB 5 1999

510(k) Summary

Proprietary Name: Howmedica Humeral Intercalary System

Common Name: Modular Humeral Component

Classification Name and Reference: 21 CFR 888.3690 Shoulder Joint Humeral (Hemi-Shoulder) Metallic Uncemented Prosthesis

Proposed Regulatory Class: Class II

Device Product Code: 77 HSD OR (87)

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: 11-24-98

The Howmedica Humeral Intercalary System is intended to be used in the management of segmental bone loss of the humerus in Oncology patients secondary to radical bone loss and/or resection due to tumors. This system (when used with the proximal bone cap described below) is intended to be used in the management of shoulder girdle resections such as the Tikhoff-Linberg procedure, which involves removal of the bone and soft tissues of the proximal humerus and shoulder girdle. The Howmedica Humeral Intercalary System is intended to be used with bone cement. There is no glenoid component associated with this system.

The Howmedica Humeral Intercalary System consists of a stem section with a body that may be attached to: 1) another stem section with body; or 2) a proximal bone cap. The stem section of the Humeral Intercalary System is fluted, and is available in diameters of 9mm and 11mm, with multiple body lengths. Both the stem segment and the proximal bone cap contain lap joints, which are joined by the use of machine screws that are available in diameters of 3 - 5 mm, and lengths of 15-20 mm.

The attachment of one stem segment to another stem segment is used when there is bone loss/resection of the mid-section of the humerus. The distal stem segment is cemented into the distal segment of the humerus, and the proximal portion is cemented into place in the proximal fragment of the humerus. The stem segments are joined by the use of the machine screws noted above.

If the proximal portion of the humerus is not present or has been resected, the bone cap segment is used proximally. There are suture holes in the bone cap to allow the passage of sutures to anchor the device proximally to the shoulder girdle (if this remains in place), or to the chest wall. The distal stem segment is cemented in place in the distal segment of the humerus. The bone cap is attached to the distal stem segment by the use of the screws noted above.

These components will be manufactured from titanium alloy (Ti-6Al-4V) which conforms to ASTM F-136.

The substantial equivalence of the Howmedica Humeral Intercalary System is based on an equivalence in intended use, material, design, and relative indications and contraindications to Howmedica's Proximal Humerus Replacement System (K954559); PMI's Proximal Humeral Segmental Replacement System (Biomet - K# unknown) and Metagen's Segmental Defect Replacement System (K980609).

Physical and Finite Element Analysis testing of the device was presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 5 1999

Mr. John F. Dichiara
Director of Regulatory Affairs and Public Policy
Howmedica Inc.
Pfizer Medical Technology Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K984202
Trade Name: Howmedica Humeral Intercalary System
Regulatory Class: II
Product Code: HSD
Dated: November 24, 1998
Received: November 24, 1998

Dear Mr. Dichiara:

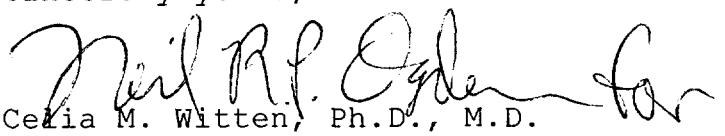
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Indications for Use

510(k) Number (if known): K984202

Device Name: Howmedica Humeral Intercalary System

Indications for Use: The Howmedica Humeral Intercalary System is intended to be used in the management of segmental bone loss of the humerus in Oncology patients secondary to radical bone loss and/or resection due to tumors. This system is intended to be used in the management of shoulder girdle resections such as the Tikhoff-Linberg procedure, which involves removal of the bone and soft tissues of the proximal humerus and shoulder girdle. The Howmedica Humeral Intercalary System is intended to be used with bone cement. There is no glenoid component associated with this system.

(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)

MRO

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984202