MAR 2 6 2004

K040128

1 of 2

Special 510(k) Summary

Proprietary Name:	Modular Replacement System (MRS) Humeral Stems
Common Name:	Modular Humeral Stems
Classification Name and Reference:	Prosthesis, shoulder, hemi-, humeral, metallic uncemented 21 CFR §888.3690
Proposed Regulatory Class:	Class II
Device Product Code:	87 HSD
Predicate Proprietary Name:	MRS Humeral Stems
Predicate Regulatory Class:	Class II
Predicate Product Code:	87 HSD
For Information contact:	Margaret F. Crowe Howmedica Osteonics Corp. DBA Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07430 Phone: (201) 831-5580 Fax: (201) 831-6038

Description/Technological Comparison

Premarket notification K954559 described the Modular Replacement system (MRS) Porous Coated Humeral Stem system. Special premarket notification K032264 expanded this product line to include non-porous coated humeral stems. Both of these stems are fabricated from cobalt-chromium alloy that conforms to ASTM F-1537. It is the intention of Howmedica Osteonics Corp. to fabricate the non-porous coated humeral stems in the MRS system from a slightly different type of cobalt-chromium – this material also conforms to ASTM F-1537, but has

slightly different metallurgical properties.

Intended Use

The intended use of the subject device is not changed by this material change:
The subject humeral stems (MRS Humeral Stems without porous coating) are intended for use with the components of the Modular Replacement System Humeral System. This device is intended for use in patients requiring reconstruction of the proximal humerus due to extensive bone loss as a result of tumor resection secondary to primary or metastatic skeletal lesions. This device is intended for use with bone cement. This is the same intended use as the predicate device in premarket notification K954559 and K032264.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2004

Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K040128
Trade/Device Name: Modular Replacement System Humeral Stems – Alternate Material
Regulation Number: 21 CFR 888.3690
Regulatory Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: HSD
Dated: March 4, 2004
Received: March 8, 2004

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1,11

Special 510(k) Premarket Notification– Modular Replacement System Humeral Stems – Alternate Material

510(k) Number (if known): K040128

Device: Modular Replacement System Humeral Stems – Alternate Material

The subject humeral stems (MRS Humeral Stems without porous coating) are intended for use with the components of the Modular Replacement System Humeral System. This device is intended for use in patients requiring reconstruction of the proximal humerus due to extensive bone loss as a result of tumor resection secondary to primary or metastatic skeletal lesions. This device is intended for use with bone cement. This is the same intended use as the predicate device in premarket notification K954559 and K032264.

(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)

Mark N Milleman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040128