K032264



AUG - 8 2003

## Special 510(k) Summary

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| Proprietary Name: | Modular Replacement System (MRS) Humeral Stems |
| Common Name: | Modular Humeral Stems |
| Classification Name and Reference: | Prosthesis, shoulder, hemi-, humeral, metallic uncemented<br>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<br>Howmedica Osteonics Corp.<br>59 Route 17<br>Allendale, New Jersey 07401-1677<br>Phone: (201) 831-5580<br>Fax: (201) 831-6038 |

**Description/Technological Comparison**

The predicate MRS Humeral Stems had a porous coated body (or seat) segment. The subject MRS Humeral Stems do not have a porous coated body segment. The subject stems are offered in the same diameters, and the same lengths as the previously released porous coated humeral stems.

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**Intended Use**

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Re: K032264
Trade/Device Name: Modular Replacement System (MRS) Humeral Stem
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: HSD
Dated: July 22, 2003
Received: July 23, 2003

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 Miriam C. Provost

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

K032264

Special 510(k) Premarket Notification– Line Extension to MRS Humeral Stems

510(k) Number (if known): K

Device: Line Extension to MRS Humeral Stems – MRS Humeral Stems without Porous Coated Body

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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

Miriam C. Provost

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

510(k) Number K032264