K062845

## 510(k) Summary of Safety and Effectiveness
## Modular Replacement Humeral and Ulna

DEC 13 2006

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| Proprietary Name: | Modular Replacement Elbow System |
| Common Name: | Modular Humeral and Ulna Components |
| Classification Name/Reference: | Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis, 21 CFR §888.3690<br><br>Elbow joint metal/polymer constrained cemented prosthesis, 21 CFR §888.3150 |
| Device Product Code: | 87 HSD, 87 JDC |
| Proposed Regulatory Class: | **Class II** |
| For Information contact: | Francisco Haro, Regulatory Affairs Specialist<br>Howmedica Osteonics Corp.<br>325 Corporate Drive<br>Mahwah, NJ 07430<br>Phone: (201) 831-5493 Fax: (201) 831-6038 |
| Date Summary Prepared: | September 22, 2006 |

Description

This submission is a line extension to the Howmedica Modular Replacement Systems for reconstruction of the humerus and ulna. Humeral components will be based on the design of the Howmedica Modular Proximal Humerus Replacement System and ulna components will be derived from the Osteonics® Total Elbow System.

Indications:

The Modular Replacement Elbow System is intended for use in Oncology patients requiring extensive reconstruction of the distal humerus, including the elbow joint and total humeral replacement, necessitated by extensive bone loss due to tumor resection. These prostheses are intended for use with bone cement as a means of intramedullary fixation.
The Modular Replacement Elbow System is also intended for use in patients requiring extensive reconstruction of the distal humerus necessitated by trauma, failed previous prosthesis, distal humeral fracture and/or dislocation, and disabling joint disease of the elbow resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.

Substantial Equivalence:

The Modular Replacement Humeral and Ulna is substantially equivalent to the Howmedica Modular Proximal Humerus Replacement System and Osteonics® Total Elbow System in regards to intended use, design, materials, and operational principles as modular replacement components. An engineering analysis was conducted to compare the strength of the subject modular replacement components to the predicate components. The results demonstrate that the subject components are substantially equivalent in strength to the predicate components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corp.
% Mr. Francisco Haro
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

DEC 13 2006

Re: K062845
Trade/Device Name: Modular Replacement Humeral and Ulna
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSD, JDC
Dated: September 22, 2006
Received: September 22, 2006

Dear Mr. Haro:

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.

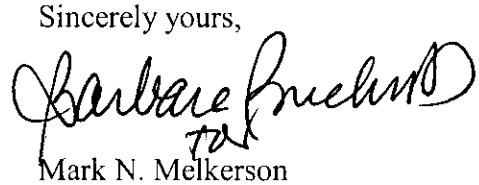
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): _____

Device Name: Modular Replacement Humeral and Ulna

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Barbara Ann M D

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

**510(k) Number** K062845