DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 corporate Boulevard
Rockville MD 20850

MAR 3 0 2005

Ms. Denise Duchene
Sr. Regulatory Affairs Specialist
Howrnedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K043374
Trade/Device Name: Duracon® Conversion and X-Small Patella with Peri-Apatite® Coating
Regulation Numbers: 21 CFR 888.3565
Regulation Names: Knee joint, patellofemorotibial, metal/polymer porous coated uncemented prosthesis
Regulatory Class: II
Product Codes: MBH
Dated: December 2,2004
Received: December 8,2004

Ms. Duchene:

This letter corrects our substantially equivalent letter of February 16, 2005 regarding the incorrect received date of January 8,2004. The correct received date is shown above.

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 (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 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 continue 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043374

Device Name: Duracon® Conversion and X-Small Patella with Peri-Apatite® Coating

Indications for Use:

The Duracon® Knee System Patella components included in this submission are intended for use in total knee arthroplasty to relieve pain and restore knee functions for indications such as:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;
- Post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee.

These products are intended to achieve fixation without the use of bone cement.

Prescription Use X OR Over-the-counter Use _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

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

510(k) Number K043374

FEB 16 2005

K043379

## Summary of Safety and Effectiveness

**Contact Person:** Denise Duchene
Sr. Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Dr.
Mahwah, NJ 07430
(201) 831-5612 (Phone)
(201) 831-6038 (FAX)

**Date:** November 12,2004

**Device:** Duracon® Conversion and X-Small Symmetric Patella with Peri-Apatite® Coating

**Classification:** Knee Joint; Patellofemorotibial; Metal/polymer; Porous-coated; Uncemented prosthesis - Class II - 21 CFR 888.3565 --Product Code: MBH

**Predicate Devices:** Duracon® Conversion and X-Small Symmetric Patella with Porous Coating for uncemented use.

**Indications for Use:** The Duracon® Patella components are for use in total knee arthroplasty to relieve pain and restore knee function for indications such as: noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and, irreparable fracture of the knee.

These products are intended to achieve fixation without the use of bone cement

**Proposed Modification:** To add a Peri-Apatite® coating to the Conversion and X-Small Symmetrical Patella components.

**Device Description:** The device patellar components of a total knee system. These components are used for the replacement of the articulating surfaces of the patella to relieve pain, instability and the restriction of motion due to degenerative bone disease, including osteoarthritis, rheumatoid arthritis, failure of other devices or trauma.

**Summary of Data:**

A risk analysis and research and development testing have been performed to demonstrate equivalence of the proposed products to the predicate devices. The testing includes porous coating characterization, contact area / stress analyses; range of motion range of constraint testing; locking mechanism testing; UHMWPE material properties in accordance with the Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA," dated January 16, 2003. The testing also includes safety testing for the Peri-Apatite coating. The results demonstrate that the Duracon Conversion Patella with Porous and Peri-Apatite coatings is safe and effective for use in total knee replacement without bone cement.