

NOV 16 1999

First Step Unicompartmental Knee System

510(k) Summary

**510(k) Summary**

Device: First Step Unicompartmental Knee  
Common Name: Unicompartmental Knee System  
Classification Name: Knee joint femorotibial metal/ polymer non-constrained cemented prosthesis 21 CFR §.888.3520  
Regulatory Class: Class II  
Product Code: 87 HSX  
For Information contact: Karen Ariemma, Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
59 Route 17  
Allendale, NJ 07401-1677  
(201) 760-8187  
Fax: (201) 934-4368

This device consists of a distal femoral resurfacing component and a proximal tibial resurfacing component. It is intended to be used to replace the medial or lateral compartments of the knee joint, specifically the femorotibial joint damaged as a result of inflammatory and non-inflammatory joint disease or trauma. These components are intended for cemented use only. The femoral component is manufactured from a cobalt-chromium alloy, which conforms to ASTM F-75. The tibial component is manufactured from ultra-high molecular weight polyethylene, which conforms to ASTM F-648.

The substantial equivalence of this device is based on equivalence in intended use, materials, design and operational principles to other predicate devices indicated for unicompartmental knee surgery. These devices include Howmedica Osteonics Corp.'s Duracon Unicompartmental Knee and SCR Uni Knee Systems.



NOV 16 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Terry Sheridan Powell  
Regulatory Affairs Team  
Stryker Howmedica Osteonics Corporation  
59 Route 17  
Allendale, New Jersey 07401-1677

Re: K992287  
Trade Name: First Step Unicompartmental Knee System  
Regulatory Class: II  
Product Code: HSX  
Dated: September 13, 1999  
Received: September 17, 1999

Dear Ms. Powell:

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.

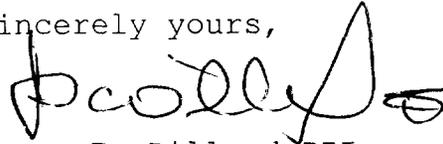
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Terry Sheridan Powell

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,



James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K 992287

Device Name: Howmedica Osteonics® First Step Unicompartmental Knee System

The First Step Unicompartmental Knee System consists of a distal femoral resurfacing component and a proximal tibial resurfacing component. The subject components of the First Step Unicompartmental Knee System are single use devices which are sold sterile. The First Step Unicompartmental Knee System is intended for cemented use only.

The specific indications and contraindications of the First Step Unicompartmental Knee System are stated in the following sections.

**Indications**

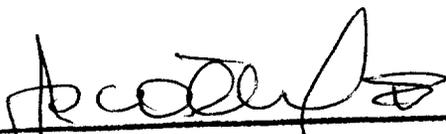
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis.
- Revision of previous unsuccessful unicompartmental knee replacement or other procedure.
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

(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)

(Optional Format 1-2-96)

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number K 992287