2/24/99

510(k) Premarket Notification
Summary of Safety and Effectiveness

Osteonics® +10 UniPolar Adaptor Sleeve

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Marybeth Naughton Regulatory Affairs Team Member
Date of Summary Preparation:	December 23, 1998

Device Identification

Proprietary Name:	Osteonics® +10 UniPolar Adaptor Sleeve
Common Name:	
Classification Name and Reference:	Prosthesis Hip, Hemi-, Femoral, Metal/Polymer Cemented or Uncemented 21 CFR §888.3390

Predicate Device Identification

The Osteonics® +10 UniPolar Adaptor Sleeve is substantially equivalent to the following competitive and/or Osteonics' devices, which have previously been determined substantially equivalent by FDA:

- Howmedica Unitrax Unipolar Neck Adjustment Sleeve Component
- Osteonics® Neck Extension for Modular Endo head

Device Description

Osteonics® +10 UniPolar Adaptor Sleeve is composed of cobalt chromium alloy and is designed to function with any size Osteonics® +0 Unipolar Endo Head (Single-Piece Unipolar Design) and any Osteonics C-Taper Femoral Stem. The Osteonics® +10 UniPolar Adaptor Sleeve is designed with both a male and a female C-taper. The female end receives the femoral stem and the male end engages the Endo Head.

The Osteonics® +10 UniPolar Adaptor Sleeve is characterized by the following features:

- A basic taper design.
- A smooth exterior finish.
- Constructed of material that has a long history of orthopedic use.

Intended Use:

The Osteonics® +10 UniPolar Adaptor Sleeve is a single-use device and may be used with all appropriately selected, legally marketed Osteonics C-Taper Femoral Stems and with any size Osteonics legally marketed +0 mm Unipolar Endo Heads (Single-Piece Unipolar Design).

Indications:

For use as a Hemi-Hip Replacement:
The indications for the use of Osteonics® +10 UniPolar Adaptor Sleeve, in keeping with those of other legally marketed Osteonics Hemi-Hip Replacement components, are as follows:

For Use as a Hemi-Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and in avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

Statement of Technological Comparison:

The substantial equivalence of the Osteonics® +10 UniPolar Adaptor Sleeve to the predicate devices identified above—in terms of intended use, materials, and design features—is based on the following.

Intended Uses:
The Osteonics®, +10 UniPolar Adaptor Sleeve, like the predicate devices cited above, is intended for use with appropriately selected, legally marketed components for Hemi-Hip replacement.

Materials:
The Osteonics® +10 UniPolar Adaptor Sleeve and the predicate devices cited above are manufactured from the same material - cobalt chromium alloy. The materials used in the subject device and the predicate devices are not new and have been used for orthopedic applications including hemi-hip replacement in the United States and Europe for many years.

Design:
The design of the Osteonics® +10 UniPolar Adaptor Sleeve is consistent with that of the predicate devices and differs in the following:

- The Howmedica Unitrax Unipolar Neck Adjustment Sleeve Components are available in four sizes while the subject device is available in only one size.
- The Howmedica Unitrax Unipolar Neck Adjustment Sleeve Components differs in dimensional specifications from the subject device. This is consistent with the use of the predicate and subject device in that each is specifically designed with dimensions to accommodate each company's accessory components.
- The Osteonics® Neck Extension for Modular Endo Head is available in three sizes while the subject device is available in only one size.
- The Osteonics® Neck Extension for Modular Endo Head differs in dimensional specifications from the subject device. This is consistent with the use of the predicate and subject device in that each is specifically designed with dimensions to accommodate appropriate Osteonics legally marketed accessory components.

None of these design differences raises any new questions of safety or effectiveness.

Summary
Based on the similarities and differences presented above, the supporting testing summary, the pre-clinical data incorporated by reference to prior submissions, and the fact that the Osteonics® +10 UniPolar Adaptor Sleeve employs standard sterilization and packaging methods, the substantial equivalence of the Osteonics® +10 UniPolar Adaptor Sleeve to other legally marketed, class II, components is demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1999

Ms. Elizabeth A. Staub
Vice President, Quality Assurance/Regulatory
Compliance/Clinical Research
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K984585
Trade Name: Osteonics® +10 UniPolar Adaptor Sleeve
Regulatory Class: II
Product Codes: KWL and KWY
Dated: December 23, 1998
Received: December 24, 1998

Dear Ms. Staub:

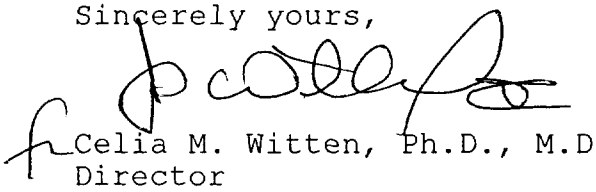
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



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

Enclosure

510(k) Number (if known): K984585

Device Name: Osteonics® +10 UniPolar Adaptor Sleeve

Indications For Use:

The indications for use of the Osteonics® +10 UniPolar Adaptor Sleeve, in keeping with those of the legally marketed predicate devices, are as follows:

For Use as a Hemi-Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and in avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X_ 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 K984585