SEP -1

K992570

Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness for the
Unitrax® C-Taper Neck Adjustment Sleeve

Proprietary Name:	Unitrax® C-Taper Neck Adjustment Sleeve
Common Name:	Adaptor for Unipolar Head
Classification Name and Reference:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR §888.3360
Proposed Regulatory Class:	Class II
Device Product Code:	87 KWL
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 Special 510(k) submission is intended to address a design modification to the predicate Unitrax® V40™ Neck Adjustment Sleeve. The Unitrax® V40™ Neck Adjustment Sleeve is a tapered sleeve component whose outer diameter mates with the bore of the Unitrax® Unipolar Head, and inner diameter mates with the trunnion neck of the femoral stem. The design modification involves changing the inner taper diameter of the current sleeve component. The modified device will allow Unitrax® Unipolar Heads to be compatible with Osteonics C-Taper femoral stems. The modified component, the Unitrax® C-Taper Neck Adjustment Sleeve, is substantially equivalent to the predicate device which was cleared for marketing via the 510(k) process. The Unitrax® C-Taper Neck Adjustment Sleeves are manufactured from wrought cobalt-chromium alloy, which conforms to ASTM F-1537. The intended use of the subject Unitrax® C-Taper Neck Adjustment Sleeve is identical to that of the Unitrax® V40™ Neck Adjustment Sleeve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 1999

Ms. Elizabeth A. Staub
Vice President
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401

Re: K992570
Trade Name: Unitrax C-Taper Neck Adjustment Sleeve
Regulatory Class: II
Product Code: KWL
Dated: July 30, 1999
Received: August 2, 1999

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 at (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): K992570

Device Name: Unitrax® C-Taper Neck Adjustment Sleeve

Indications For Use:

The indications for use of the Unitrax® C-Taper Neck Adjustment 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/neck
- Osteo- and post traumatic arthritis

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use No

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992570