K014226 page 1 of 1

JAN 2 5 2002

Special 510(k) Summary - Device Modifications for the
UNITRAX® MODULAR UNIPOLAR SYSTEM

Proprietary Name:	Unitrax® Modular Unipolar System
Common Name:	Unipolar Head
Classification Name and Reference:	888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
Proposed Regulatory Class:	II
Device Product Code:	KWL
For Information Contact:	Jennifer A. Daudelin, Regulatory Affairs Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 (201) 831-5379 Fax: (201) 760-8435

This Special 510(k) submission is intended to address design, manufacturing process, and material modifications to the Unitrax® Modular Unipolar System. The Unitrax® component is a unipolar head that accepts a neck adjustment adaptor or sleeve. The neck adjustment sleeve is then assembled to the trunnion of the desired Howmedica Osteonics femoral stem. The design modification to the unipolar head involves a reduction in the wall thickness and removal of the inner "ribs". The manufacturing process modification involves changing the size 45mm and 46mm components from machined to cast parts which results in a material change from ASTM F1537 to ASTM F75. The modified component is substantially equivalent to the predicate device which was cleared for marketing via the 510(k) process in 510(k) #K902365. The Unitrax® Modular Unipolar Heads are manufactured from Vitallium® (CoCr) Alloy which conforms to ASTM standards F75 (cast) and F1537 (wrought). The intended use of the modified Unitrax® Modular Unipolar Heads is identical to that of the unmodified Unitrax® Modular Unipolar Heads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Ms. Jennifer A. Daudelin
Regulatory Affairs
Howmedica Osteonics, Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K014226
Trade/Device Name: Unitrax® Modular Unipolar System
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Cemented or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWL
Dated: December 21, 2001
Received: December 26, 2001

Dear Ms. Daudelin:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Mark N Melkerson

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

Enclosure

Indications for Use

page 1 of 1

510(k) Number (if known): K014226

Device Name: Unitrax® Modular Unipolar System

Indications for Use:
The Unitrax® Modular Unipolar System is intended to be used with a Howmedica Osteonics hip stem. When assembled to a hip stem, the resultant component functions in a similar fashion to a fixed head endoprosthesis. The endoprosthesis is used as a hemi-arthroplasty for the following indications: femoral neck fractures, idiopathic avascular necrosis and non-unions.

(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)

for Mark N. Milhauser

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

510(k) Number K014226