510(k) Summary of Safety and Effectiveness for the T2 Arthrodesis Nail System

Proprietary Name:	T2 Arthrodesis Nail System
Common Name:	Intramedullary Nail
Classification Name and Reference	Intramedullary Fixation Rod 21 CFR §888.3020
Regulatory Class:	Class II
Device Product Code:	87 HSB
For Information contact:	Karen Ariemma, Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 760-8187 Fax: (201) 760-8435
Date Summary Prepared:	February 4, 2002

Description:
The T2 Arthrodesis Nails have a one-piece round profiled shaft design. The nails are cannulated and have a closed-section design with distal rounded end. The T2 Arthrodesis is available in lengths from 540 mm to 780 mm in 40 mm increments, and in diameters from 10 mm to 15 mm.

Intended Use:
The subject T2 Arthrodesis Nail System is an internal fixation system comprised of intramedullary nails and the related locking screws, compression screws and end caps. The subject device is intended to provide strong and stable internal fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

Substantial Equivalence:
The design and function of the T2 Arthrodesis Nail is substantially equivalent to that of the predicate devices. Both the subject and predicate systems offer nails in varying lengths, and offer a combination of locking screws, compression screws and end caps, the combination of which varies depending on which system is used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2002

Ms.Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Re: K020384
Trade/Device Name: T2 Arthrodesis Nail System
Regulation Number: 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: February 4, 2002
Received: February 5, 2002

Dear Ms. Ariemma:

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

Enclosure

510(k) Number (if known): K 020384

Device Name: T2 Arthrodesis Nail System

Indications for Use

The T2 Arthrodesis Nail is indicated for long bone internal fixation, which may include the following:

The subject device is indicated for long bone fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Ipsilateral femur fractures
- Failed external fixation, nonunions and malunions
- Periarticular fractures where repair is not possible
- Aseptic failed total knee arthroplasty
- Knee arthrodesis

(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 Milhous

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

510(k) Number K020384