JUL 2 9 2005

K051590

510(k) Summary of Safety and Effectiveness: T2® Ankle Arthrodesis Nail

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430
For Information contact:	Vivian Kelly, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	July 25, 2005

Device Identification

Proprietary Name:	T2® Ankle Arthrodesis Nail
Common Name:	Intramedullary Nail
Classification Name and Reference:	Intramedullary Fixation Rod and Accessories, 21 CFR §888.3020
Device Product Code:	87 HSB

Description:
This 510(k) submission is a line extension to the T2® Nailing System to add an ankle arthrodesis nail and additional accessories to the system. The nails are inserted using an opened or closed technique and can be locked in static, dynamic or compression mode. The T2® Ankle Nails and accessories are intended for single use only.

Intended Use:
The T2® Ankle Arthrodesis Nail is intended for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot. Examples of specific indications include:

- Post-traumatic or primary Arthrosis
- Previously infected arthrosis (second degree)
- Revision of Failed Ankle Arthrodesis
- Failed Total Ankle Replacement
- Avascular Necrosis of the Talus (requiring tibiocalcaneal arthrodesis)
- Neuroarthropathy or Neuromuscular Deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid Arthritis with severe deformity such as rheumatoid hindfoot
- Ostheoartritis
- Nonunions or Pseudarthrosis of hindfoot and distal tibia
- Malunited tibial pilon fracture
- Charcot foot
- Severe endstage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

Substantial Equivalence:
The T2® Ankle Arthrodesis Nail is substantially equivalent to other legally marketed ankle nails in regards to design, materials, indications and operational principles. Testing demonstrated comparable mechanical strength to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2005

Ms. Vivian Kelly, RAC
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K051590
Trade/Device Name: T2® Ankle Arthrodesis Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB
Dated: June 14, 2005
Received: June 15, 2005

Dear Ms. Kelly:

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051590

Device Name: T2® Ankle Arthrodesis Nail

Indications for Use:

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- Severe endstage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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