OCT 8 - 2004

K042396

510(k) Summary of Safety and Effectiveness: T2 Proximal Humeral Nail Line Extension

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:	September 1, 2004

Device Identification

Proprietary Name:	T2 Proximal Humeral 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 new types of Proximal Humeral Nails. The nails are inserted using an opened or closed technique and can be statically or dynamically locked. The T2 Proximal Humeral Nails are intended for single use only.

Intended Use:

The T2 Proximal Humeral Nail is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact calotte, or Humeral Fractures according to Neer-Classification.

Substantial Equivalence:

The T2 Proximal Humeral Nail also has the same basic design concepts as the predicate devices. FEA Analysis demonstrated comparable mechanical properties to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 - 2004

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

Re: K042396
Trade/Device Name: T2Proximal Humeral Nail
Regulation Number: 21CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 1, 2004
Received: September 2, 2004

Dear Ms. Montemurro:

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/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

510(k) Number (if known):

Device Name: T2 Proximal Humeral Nail

Indications for Use:

The T2 Proximal Humeral Nail is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact calotte, or Humeral Fractures according to Neer-Classification.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

for _____

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K042396