K082018

510(k) Summary of Safety and Effectiveness
T2™ Flexible Nail

OCT 10 2008

Proprietary Name:	T2™ Flexible Nail
Common Name:	Intramedullary Nail
Classification Name/Reference:	Intramedullary Fixation Rod 21 CFR §888.3020
Device Product Code:	87 HSB
Proposed Regulatory Class:	Class II
For Information contact:	Francisco Haro, Senior Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	July 15, 2008

Description:

The T2™ Flexible Nail is a flexible nail designed to be curved so that the apex of the arc is located in the fracture site. It has a non-cannulated, one-piece, round shaft design that can be cut to size intraoperatively. The nail is available in eight diameters and two lengths. The nails will be available sterile and non-sterile in titanium alloy and stainless steel.

Indications:

The T2™ Flexible Nail is intended for the temporary stabilization of bone segments or fragments until bone consolidation has been achieved. This includes upper extremity fractures of all patients and lower extremity fractures of pediatric or small-statured patients.
Specific indications include:

- Fixation of mid-diaphyseal, proximal and distal fractures of the femur, tibia, and fibula in pediatric and small-statured patients.
- Fixation of mid-diaphyseal, proximal and distal fractures of humerus and forearm fractures in all patients.

Substantial Equivalence:

The subject system is substantially equivalent to the predicate nailing systems for the stabilization of long bone fractures using a closed technique. The supporting information included in the following pages has sufficiently demonstrated the equivalence of the subject device to its predicates in regards to intended use, design, materials and operational principles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2008

Howmedica Osteonics Corp.
c/o Mr. Francisco Haro
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, NJ 07430

Re: K082018
Trade/Device Name: T2™ Flexible Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 15, 2008
Received: July 16, 2008

Dear Mr. Haro:

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" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
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): K082018

Device Name: T2™ Flexible Nail

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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)~~

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K082018