510(k) Summary of Safety and Effectiveness for the Titan Tibial Nail

DEC 15 2000

Proprietary Name:	Titan Tibial Nail
Common Name:	Tibial Nail
Classification Name and Reference	Intramedullary Fixation Rod 21 CFR §888.3020
Device Product Code:	HSB, Rod, Fixation, Intramedullary and Accessories
For Information Contact:	Karen Ariemma Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677

The Titan Tibial Locking Nail is a cylindrical tube manufactured from titanium alloy slightly bowed to accommodate the shape of the tibia. Locking screws, compression screws and an end cap are manufactured from titanium alloy and are used with the nails. The Titan Tibial Locking Nail is available in three versions, each differing from the other only in diameter, length and number and orientation of screw holes.

The design and function of the Titan Tibial Locking Nail is substantially equivalent to that of the predicate devices. Both the subject and predicate systems offer tibial 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

DEC 15 2000

Ms. Elizabeth A. Staub
Vice President, Quality Assurance/Regulatory Compliance/Clinical Research
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401

Re: K003018
Trade Name: Titan Tibial Nail
Regulatory Class: Class II
Product Code: HSB
Dated: September 26, 2000
Received: September 27, 2000

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/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

510(k) Number (if known): K____

Device Name: Titan Tibial Nail System

Indications For Use:

The Titan Tibial Locking Nail is intended to provide temporary stabilization of various types of fractures, malunion and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compressed locked.

The Titan Tibial Nail System is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K003018

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____