

DEC 16 1998

K984353

**SPECIAL 510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Osteo 9mm IC Tibial Nail**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Kate Sutton
Regulatory Affairs Specialist

Date Summary Prepared:

December 1, 1998

Device Identification

Proprietary Name:

Osteo 9mm IC Tibial Nail

Common Name:

Intramedullary Nail, Tibial Nail

Classification Name and Reference:

Intramedullary Fixation Rod
21 CFR §888.3020

Predicate Device Identification

The design and function of the Osteo 9mm IC Tibial Nail is substantially equivalent to that of the predicate Osteo 9mm IC Tibial Nail. The subject and predicate systems offer tibial nails in varying lengths, and utilize compression screws, a locking screw, and an end cap.

Device Description

The Osteo 9mm IC Tibial Nail is a cylindrical, cannulated stainless steel tube. Tibial Nails provide for the alignment and stabilization of long bone fractures while maintaining limb length and resisting rotation of the fracture segments. The Osteo 9mm IC Tibial Nail is implanted in association with proximal and distal locking screws with the aid of several associated Class I manual surgical instruments. The Tibial Nails are stainless steel tubes gun-drilled from a solid Stainless Steel bar. Three external longitudinal grooves are pressed into the tube and are intended to provide greater resistance to bending and increased torsional stability. The Osteo 9mm IC Tibial Nail is available in lengths from 240mm to 420mm in 15mm increments, and has a distal shaft diameter of 9mm. A compression screw and locking screw may be used with the Tibial Nail. An end cap is also available for use with the Tibial Nail. An end cap is used if a compression screw has not been used.

The following changes have been made to the modified Tibial Nail.

- 1) The wall thickness of the Tibial Nail has been increased by 0.2mm, resulting in a reduction in the distal cannulation diameter from 6.4mm to 6.0mm. The 9mm outer diameter of the distal end of the nail remains the same.
- 2) The length of the \varnothing 11mm proximal portion of the Tibial Nail was increased from 33mm to 60mm, and the proximal portion of the nail is tapered at a 2° angle from \varnothing 11mm to \varnothing 9mm.
- 3) In order to reduce irritation of the patella tendon, the proximal anterior end of the modified Tibial Nail features a small 10° chamfer 5.7mm in length.

Intended Use

The Osteo 9mm IC Tibial Nail is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Static and compression locking
- Transverse and short oblique fractures
- Pseudarthrosis
- Correction osteotomies

Statement of Technological Comparison

The subject modified Osteo 9mm IC Tibial Nail components are substantially equivalent in design and intended use to the predicate unmodified Osteo 9mm IC Tibial Nail components.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kate Sutton
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K984353
Trade Name: Osteo 9mm IC Tibial Nail
Regulatory Class: II
Product Code: HSB
Dated: December 1, 1998
Received: December 7, 1998

Dear Ms. Sutton:

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.

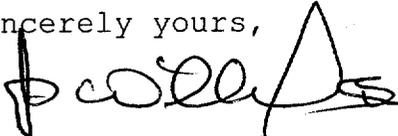
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Kate Sutton

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


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

Enclosure

510(k) Number (if known): K984353

Device Name: Osteo 9mm IC Tibial Nail

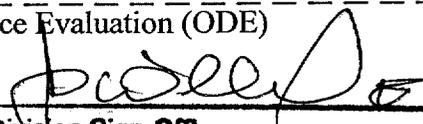
Indications For Use:

The indications for the use of the Osteo 9mm IC Tibial Nail remain unchanged and are as follows:

- Static and compression locking
- Transverse and short oblique fractures
- Pseudarthrosis
- Correction osteotomies

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K984353

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)