OCT 27 1998

K983339

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Osteo DynaTroc™ Proximal Femoral 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:

September 21, 1998

Device Identification

Proprietary Name:

Osteo DynaTroc™ Proximal Femoral Nail

Common Name:

Intramedullary Nail, Femoral Nail

Classification Name and Reference:

Intramedullary Fixation Rod
21 CFR §888.3020

Predicate Device Identification

The design and function of the Osteo DynaTroc™ Proximal Femoral Nail is substantially equivalent to that of the predicate Synthes PFN, the predicate Richards IMHS Nail, and the predicate Howmedica Gamma Locking Nail. The subject and predicate systems offer proximal femoral nails in varying lengths and diameters, and utilize a combination of locking screws, end caps, lag screws, and compression screws, the combination of which varies depending on which manufacturer's product is being used.

Device Description

The Osteo DynaTroc™ Proximal Femoral Nail is a cylindrical, cannulated titanium alloy tube with three distal slots, which is slightly bowed (4 degrees) in the medial-lateral plane to accommodate the shape of the proximal femur. The Osteo DynaTroc™ Proximal Femoral Nail is available in three different proximal/distal nail diameters to accommodate the differing morphology of small, average, and larger size patients. The distal tip of the nail contains three slots that are intended to reduce bone stresses normally incurred during insertion of the nail and post operative healing. Two locking holes, one round and one oval-shaped, are located toward the distal end of the nail but are superior to the

distal slots. The superior end of the nail contains two screw holes to accommodate lag screws. The superior lag screw hole accommodates a 6.5mm diameter lag screw, and the inferior lag screw hole accommodates a 10mm diameter lag screw. All screw holes are oriented in the medial-lateral plane. An end cap (protection screw) is screwed into the proximal end of the nail to prevent excessive tissue ingrowth. The Osteo DynaTroc™ Proximal Femoral Nail is available in lengths of 180mm, 205mm, and 220mm, and in proximal/distal diameters of 17mm/12mm, 16mm/11mm, and 15mm/10mm. The surfaces of the Osteo DynaTroc™ Proximal Femoral Nail and related components are anodized with a Type II coating process.

Intended Use

The Osteo DynaTroc™ Proximal Femoral Nail is indicated for proximal fracture fixation, which includes the following:

- Intertrochanteric fractures
- Pertrochanteric fractures
- High subtrochanteric fractures

Statement of Technological Comparison

The subject Osteo DynaTroc™ Proximal Femoral Nail components are substantially equivalent in design and intended use to the predicate devices offered by Synthes, Richards, and Howmedica.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1998

Ms. Elizabeth A. Staub
Director, Quality Assurance and Regulatory Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K983339
Trade Name: Osteo DynaTroc™ Proximal Femoral Nail
Regulatory Class: II
Product Code: HSB
Dated: September 21, 1998
Received: September 23, 1998

Dear Ms. Staub:

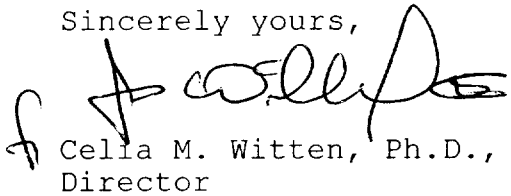
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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): K_____

Device Name: Osteo DynaTroc™ Proximal Femoral Nail

Indications For Use:

The Osteo DynaTroc™ Proximal Femoral Nail is indicated for proximal femoral fracture fixation, which includes the following:

- Intertrochanteric fractures
- Pertrochanteric fractures
- High subtrochanteric fractures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X 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 K983339