

K982601

SEP 14 1998

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Osteo IC Retrograde/Antegrade 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:

July 22, 1998

Device Identification

Proprietary Name:

Osteo IC Retrograde/Antegrade 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 IC Retrograde/Antegrade Femoral Nail is substantially equivalent to that of the predicate Synthes Titanium Distal Femoral System, the predicate Synthes Titanium Unreamed Femoral Nail System, the predicate AIM Titanium Femoral Nail, manufactured by ACE Medical, and the predicate Richards Retrograde Nail. The subject and predicate systems offer femoral nails in varying lengths, and utilize a combination of locking screws, end caps, nuts, and washers, the combination of which varies depending on which manufacturer's product is being used.

Device Description

The Osteo IC Retrograde/Antegrade Femoral Nail is a cylindrical, cannulated titanium alloy tube, slightly bowed to accommodate the shape of the femur. The Osteo IC Retrograde/Antegrade Femoral Nail may be inserted into the femoral canal using either a retrograde or antegrade surgical approach. The Osteo IC Retrograde/Antegrade Femoral Nail is available in three versions, each in lengths from 240mm to 500mm in 20mm increments, and in diameters from \varnothing 9mm to \varnothing 15mm in 1mm increments. A compression screw and locking screw may be used with the Femoral Nail. An end screw and an

end cap are also available for use with the Femoral Nail. An end cap or end screw is used if a compression screw has not been used. The end screw is used when the Femoral Nail has been inserted via a retrograde approach. The end cap is used when the Femoral Nail has been inserted via an antegrade approach.

Intended Use

The Osteo IC Retrograde/Antegrade Femoral Nail is indicated for long bone fracture fixation, specifically femoral fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Supracondylar fractures, including those with intra-articular extension
- Ipsilateral femur/tibia fractures
- Fractures proximal to a total knee arthroplasty
- Fractures distal to a hip implant
- Nonunions and malunions

Statement of Technological Comparison

The subject Osteo IC Retrograde/Antegrade Femoral Nail components are substantially equivalent in design and intended use to the predicate devices offered by Synthes, ACE Medical, and Richards.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1998

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

Re: K982601
Osteo IC Retrograd/Antegarde Femoral Nail
Regulatory Class: II
Product Code: HSB
Dated: July 22, 1998
Received: July 27, 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.

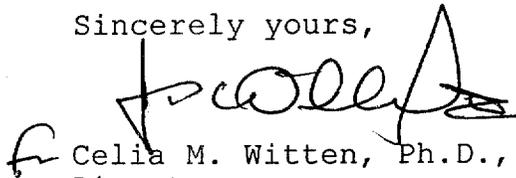
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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): K 982601

Device Name: Osteo IC Retrograde/Antegrade Femoral Nail

Indications For Use:

The Osteo IC Retrograde/Antegrade Femoral Nail is indicated for long bone fracture fixation, specifically femoral fracture fixation, which may include the following:

- Open and closed femoral fractures.
- Pseudarthrosis and correction osteotomy.
- Pathologic fractures, impending pathologic fractures, and tumor resections.
- Supracondylar fractures, including those with intra-articular extension.
- Ipsilateral femur/tibia fractures.
- Fractures proximal to a total knee arthroplasty.
- Fractures distal to a hip implant.
- Nonunions and malunions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

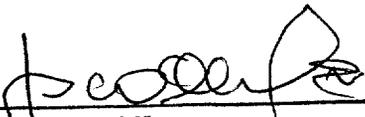
Prescription Use X

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 K982601