Summ

K990152

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Osteo IC Retrograde/Antegrade Femoral Nail - Accessories

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 201-825-4900
Contact Person:	Kate Sutton (or Marybeth Naughton) Regulatory Affairs Specialist
Date Summary Prepared:	January 12, 1999

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 nut and washer is substantially equivalent to the nut and washer of 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.

Device Description

The nut and washer for the Osteo IC Retrograde/Antegrade Femoral Nail are manufactured from ASTM F136-96 titanium alloy (Ti6Al-4V) and are anodized with a Type II coating process. The washer is 1.2mm thick, has a total diameter of 12mm, and a through-hole diameter of 5.2mm. The nut is T-shaped with an outer shaft diameter of 7mm, and inner shaft diameter of 5.5mm and a total length of 12mm. The head of the nut had a diameter of 12mm. The inner shaft of the nut is threaded in order to accommodate the threads of a locking screw. The washer is placed between the head of the locking screw and the bone surface. The nut is placed on the distal end of the screw. The 7mm diameter shaft of the nut sits below the surface of the bone, and the rounded 12mm diameter head of the nut will sit on the surface of the bone. All components of the Osteo IC Retrograde/Antegrade Femoral Nail are provided both sterile and non-sterile.

Intended Use

The Osteo IC Retrograde/Antegrade Femoral Nail and its accessories are 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 nut and washer are substantially equivalent in design and intended use to the predicate nut and washer offered by Richards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 1999

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

Re: K990152
Osteo IC Retrograde/Antegrade Femoral Nail - Accessories
Regulatory Class: II
Product Code: HSB
Dated: January 12, 1999
Received: January 19, 1999

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 990152

Device Name: Osteo IC Retrograde/Antegrade Femoral Nail - Accessories

Indications For Use:

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- Open and closed femoral fractures.
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- 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990152

Prescription Use X OR Over-The-Counter Use ____

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