

DEC 4 1998

510(k) Summary
Intramedullary Nail System

K98 3942

Submitter's name: Smith & Nephew, Inc
Submitter's address: 1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number: 901/399-5861
Contact person: JoAnn Kuhne
Date summary prepared: November 4, 1998

Trade or proprietary device name: Intramedullary Nail
Common or unusual name: Intramedullary Nail
Classification name: Title 21 CFR 888.3020 - Intramedullary Fixation Rod Class II
Legally marketed predicate device: Trimax Nail System

Subject device description:

The *Intramedullary Nail System* includes femoral, tibial, ulna/radial, humeral, ankle fusion, knee fusion nails and accessories. Components are manufactured from stainless steel and UHMWPE.

Subject device intended use:

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; and bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability are indicated for the following: subtrochanteric fractures with lesser trochanteric involvement; ipsilateral femoral shaft/neck fractures; and intertrochanteric fractures.

In addition to the indications for interlocking intramedullary nails, devices that utilize a retrograde femoral surgical approach are indicated for the following: severely comminuted supracondylar fractures with or without difficult intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; and fractures above total knee implants.

Indications for the ReVision Nail include the following: degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations in the hindfoot; tibio-calcaneal arthrodesis; combined arthrodesis of the ankle and sub-talar joints; avascular necrosis of the ankle and sub-talar joints; failed total ankle replacement with sub-talar intrusion; failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pylon fractures with trauma to the sub-talar joint.

Knee Fusion Nails are intended for intramedullary knee arthrodesis.

Ender Nails are indicated as follows: fracture of the neck, trochanteric, and subtrochanteric region of the femur; distal femoral fractures with a distal fragment 10 cm or longer; tibial shaft fractures; and proximal humeral fractures.

510(k) Summary (cont.)
Intramedullary Nail System

Technological characteristics:

The *Intramedullary Nail System* is similar to the devices listed below.

1. Titanium Femoral/Recon Antegrade Nail and the Femoral Retrograde/Tibial Nail (Smith & Nephew Orthopaedics)
2. TriMax Femoral/Recon Antegrade Nail and the 1 piece Femoral Retrograde Nail (Smith & Nephew Orthopaedics)
3. AIM Femoral, Supracondylar, Tibial Nails (DePuy Ace)
4. Titanium Unreamed Femoral Nail System (Synthes)
5. Kuntscher Nails for the femur, tibia, ulna/radius, and humerus (Smith & Nephew Orthopaedics)
6. Uniflex Tibial and Humeral Nail Systems (Biomet)
7. Grosse & Kempf Tibial Nail (Howmedica)
8. Alta Tibial/Humeral Modular Trauma System (Howmedica)
9. True/Flex IM Rod System for the Humerus, Ulna and Radius (Applied Osteo Systems)
10. Small Bone Locking Nail (Biomet)
11. Polarus Humeral and AF Rods (Acumed)
12. Atlas Fracture Proximal Humeral Nail (Biomet)
13. Tibia-Talus-Calcaneus Nail (Smith & Nephew Orthopaedics)
14. Knee Fusion Nail (Smith & Nephew Orthopaedics)

All of the devices listed above are similar in design to the *Intramedullary Nail System*. The new devices have the same technological characteristics as the predicate device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. JoAnn M. Kuhne
Manager, Regulatory Affairs
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K983942
Trade Name: Intramedullary Nail System
Regulatory Class: II
Product Code: JDS
Dated: November 4, 1998
Received: November 5, 1998

Dear Ms. Kuhne:

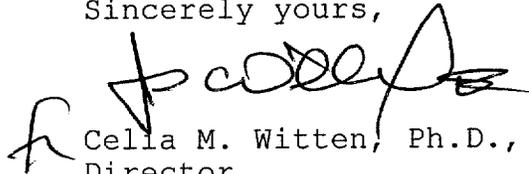
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 pre-market 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,

A handwritten signature in black ink, appearing to read 'h Cella M. Witten', is written over the typed name.

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

Enclosure

**Abbreviated Premarket Notification
Indications Statement
Intramedullary Nail System
Smith & Nephew Inc.**

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

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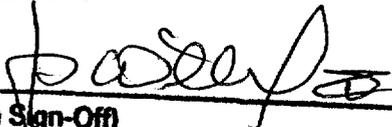
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Prescription Use _____
(Per 21 CFR 801.109)



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

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