K981529

JUL 9 1998

Summary of Safety and Effectiveness
Titanium Nail System

Substantial Equivalence Information

The Titanium Nail System is similar to the following systems:

1. TriMax Antegrade and Retrograde Nails (Smith & Nephew Orthopaedics)
2. Kuntscher Nail (Smith & Nephew Orthopaedics)
3. Aim Antegrade Femoral, Retrograde Femoral and Tibial Nails (Ace)
4. Unreamed Femoral (URFN) and Tibial Nails (Synthes)
5. Retrograde Femoral Nail (Biomet)
6. Ace ART Femoral Nail (DePuy Ace)

All of the devices listed above are similar in design to the Titanium Nail System. The safety and effectiveness of the Titanium Nail System is based on the long history of use of these devices in the market place.

Device Description

The Titanium Nail System includes femoral and tibial nails and screws. All components are manufactured from titanium alloy.

Indications for 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; 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 (i.e. Femoral/Recon Antegrade Nail) 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 (i.e. Retrograde/Tibial and Supracondylar Nails) 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; fractures above total knee implants.

The Titanium Nail System is intended to be removed upon fracture healing.

The Titanium Nail System is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 1998

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

Re: K981529
Trade Name: Titanium Intramedullary Nail, Titanium Locking Screw
Regulatory Class: II
Product Code: JDS
Dated: April 28, 1998
Received: April 29, 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 (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,

for 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

K981529

Indications Statement

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Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981529