K040656

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MAY 2 5 2004

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
Intramedullary Hip Screw

Contact Person and Address
Janet Akil
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, TN 38116
(901) 399-5153

Date of Summary: March 11, 2004

Name of Device: Intramedullary Hip Screw
Common Name: Intramedullary Hip Screw Nails and Accessories

Device Classification Name
21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories – Class II

Indications for Use
Intramedullary Hip Screws are indicated for intracapsular fractures of the femoral neck; trochanteric or subtrochanteric fractures; osteotomies for patients with diseases or deformities of the hip; hip arthrodesis; supracondylar fractures and distal femoral fractures using a supracondylar plate; ipsilateral femoral shaft/neck fractures; intertrochanteric fractures; femoral neck fractures; subcapital fractures; comminuted neck and shaft fractures; femur reconstruction following tumor resection; leg length discrepancies secondary to femoral inequality; and prophylactic nailing of impending pathologic fractures. Smith & Nephew, Inc. Intramedullary Hip Screws are for single use only.

Mechanical and Clinical Data
A review of the mechanical test data indicated that the Intramedullary Hip Screw is equivalent to predicate devices currently used clinically and is capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information
The substantial equivalence of the Intramedullary Hip Screw is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – Smith & Nephew's Intramedullary Hip Screw (K954712), Titanium Nail System (K981529), Trauma Internal Fixation System (K993289), Intramedullary Nail System (K983942) and TriGen InterTAN (K040212).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2004

Ms. Janet Akil
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K040656
Trade/Device Name: Intramedullary Hip Screw
Regulation Number: 21 CFR 888.3030 and 21 CFR 888.3040
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories, and Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: KTT and HWC
Dated: March 11, 2004
Received: March 12, 2004

Dear Ms. Akil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

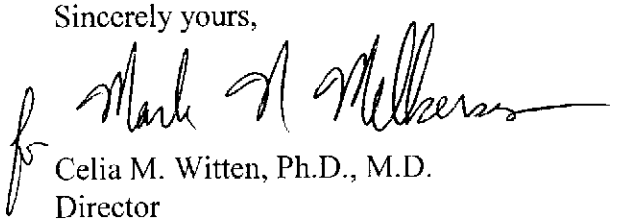
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K040656

Device Name: Intramedullary Hip Screw

Indications For Use: Intramedullary Hip Screws are indicated for intracapsular fractures of the femoral neck; trochanteric or subtrochanteric fractures; osteotomies for patients with diseases or deformities of the hip; hip arthrodesis; supracondylar fractures and distal femoral fractures using a supracondylar plate; ipsilateral femoral shaft/neck fractures; intertrochanteric fractures; femoral neck fractures; subcapital fractures; comminuted neck and shaft fractures; femur reconstruction following tumor resection; leg length discrepancies secondary to femoral inequality; and prophylactic nailing of impending pathologic fractures. Smith & Nephew, Inc. Intramedullary Hip Screws are for single use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040656