

MAR 23 2004

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Smith & Nephew, Inc.
Summary of Safety and Effectiveness
TriGen Trochanteric Antegrade Nail

Contact Person and Address

Kim Kelly
Project Manager, Regulatory/Clinical Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, TN 38116
(901) 399-6566

Date of Summary: February 20, 2004

Name of Device: TriGen Trochanteric Antegrade Nail
Common Name: Intramedullary Nail

Device Classification Name

21 CFR 888.3020 Intramedullary fixation rod – Class II

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 are indicated for the following: subtrochanteric fractures with lesser trochanteric involvement; ipsilateral femoral shaft/neck fractures; and intertrochanteric fractures. The Smith & Nephew, Inc. Trochanteric Antegrade Nail is for single use only.

Mechanical and Clinical Data

A review of the mechanical test data indicated that the TriGen Trochanteric Antegrade Nail is equivalent to devices currently used clinically and is capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information

The substantial equivalence of the TriGen Trochanteric Antegrade Nail is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – Smith & Nephew's Titanium Nail System (K981529) and Intramedullary Nail System (K983942).



MAR 23 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kim Kelly
Project Manager, Clinical/Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K040462

Trade/Device Name: TriGen Trochanteric Antegrade Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: February 20, 2004
Received: March 8, 2004

Dear Ms. Kelly:

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.

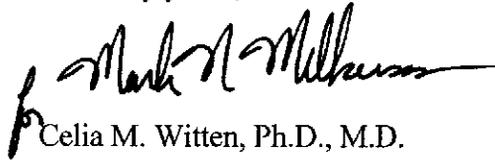
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Kim Kelly

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a long horizontal stroke at the end.

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

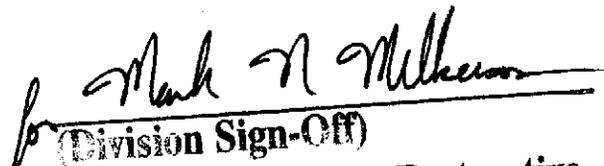
Enclosure

TriGen Trochanteric Antegrade Nail
Indications Statement

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

510(k) Number K040462

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____