K051557

510(k) Summary of Safety and Effectiveness

TriGen® Retrograde Femoral, Supracondylar, and Tibial Nails

Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

Date: June 8, 2005

JUN 3 0 2005

Contact Person: David Henley, Senior Regulatory Affairs Specialist
Proprietary Name: **TriGen® Retrograde Femoral, Supracondylar and Tibial Nails**
Common Name: Intramedullary Nail
Classification Name and Reference: 21 CFR 888.3020 – Intramedullary Fixation Rod, Class II
Device Product Code and Panel Code: JDS / Orthopaedics / 87

Device Description:
The subject devices are line additions to the TriGen® Intramedullary Nail System. These line additions are comprised of retrograde femoral, supracondylar, and tibial intramedullary nails and a nail cap. All described components are manufactured from titanium material.

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 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 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.

Intramedullary locking nails (i.e. **TriGen® Nails**) are for single use only.

Technological Characteristics:
The principle of operation of the subject devices is identical to that of the predicates. There are no changes in intended use, performance specifications or method of operation. A review of the test data for the subject devices indicates that they are equivalent to the predicate devices currently in clinical use and are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information:
Substantial equivalence for TriGen® Retrograde Femoral, Supracondylar and Tibial Nails is based on its similarities in indications for use, design features, operational principles, and material composition when compared to the predicate devices cleared under the following submissions: **K981529**, Smith & Nephew Titanium (TriGen®) Intramedullary Hip System; **K983942**, Smith & Nephew Intramedullary Nail System; **K032722**, TriGen® Straight Humeral Nail; and **K040212**, TriGen® InterTAN Nails.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2005

Mr. David Henley
Smith and Nephew Incorporated
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K051557
Trade/Device Name: TriGen® Retrograde Femoral, Supracondylar, and Tibial Nails
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: JDS
Dated: June 10, 2005
Received: June 13, 2005

Dear Mr. Henley:

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 (240) 276-0120 . 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): _____

Device Name: TriGen® Retrograde Femoral, Supracondylar, and Tibial Nails

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 long bones being treated.

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Intramedullary locking nails (i.e. **TriGen® Nails**) are for single use only.

Prescription Use ___X___ and/or **Over-the-Counter Use** _____
(Per 21 CFR 801, 109) (Optional Format 1-2-96)

(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, and Neurological Devices

510(k) Number K051557