K092748

510(k) Summary of Safety and Effectiveness
SURESHOT™ TAN Nails and Accessories

APR 2 3 2010

Submitted By: Smith & Nephew, Inc.
Orthopaedics
1450 Brooks Road
Memphis, TN 38116

Date: September 4, 2009

Contact Person: David Henley, Regulatory Affairs Project Manager
Tel: (901) 399-6487 Fax: (901) 398-5146

Proprietary Name: **SURESHOT™ TAN Nails and Accessories**

Common Name: Intramedullary Nails and Accessories

Classification Name and Reference: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories - Class II

Device Product Code and Panel Code: JDS / Orthopedics / 87

Device Description:
The subject devices are comprised of intramedullary nails and accessories such as lag screws, compression screws and set screws for use in the femur. All described components are manufactured from titanium material. The subject devices are available in the following size ranges:

Device Type	Available Range of Diameters	Available Length Range
Nails	9mm – 13mm	32cm – 42cm
Lag Screws	8.64mm (one diameter only)	70mm – 125mm
Compression Screw s	6.22mm (one diameter only)	30mm – 120mm
Set Screws	6.6mm (one diameter only)	25.4mm – 39.3mm

Intended Use:
SURESHOT™ TAN Nails are indicated for fractures of the femur including 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; and for fixation of fractures that occur in and between the *proximal third* and *distal fourth* of the femur.

In addition, SURESHOT™ TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following: subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; and intracapsular fractures.

Technological Characteristics:
Components comprising **SURESHOT™ TAN Nails and Accessories** are very similar to legally marketed devices listed below in that they share very similar indications for use (compared to devices cleared under K981529, K040212, K040462, K061019, K050226 and K010801), are manufactured from identical material, and incorporate very similar technological design characteristics.

Substantial Equivalence Information:
When compared to the predicate devices listed below, substantial equivalence is based on similarities with regard to overall indications for use, material composition, and technological design characteristics.

- Titanium Nail System (TriGen™ Titanium Intramedullary Nail System) – K981529
- TriGen™ InterTAN Nail – K040212
- TriGen™ Trochanteric Antegrade Nail – K040462
- TriGen™ Meta-Nails Retrograde Femoral and Tibia Nails – K061019
- Asian Intramedullary Hip Screw (IMHS) – K050226
- T2 Femoral Nail (Stryker/Howmedica/Osteonics Corp.) – K010801

To further support a determination of substantial equivalence, various types of pre-clinical testing were conducted on the subject devices in comparison against one or more of the previously cleared predicate devices described above. The types of pre-clinical testing included: *finite element analysis*, *construct fatigue testing* of a nail construct with appropriate accessory devices and *axial pullout testing* of the lag screw from appropriate test media.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 2 3 2010

Smith and Nephew Inc.
% Mr. David Henley
Regulatory Affairs Project Manger
1450 Brooks Road
Memphis, Tennessee 38116

Re: K092748
Trade/Device Name: SURESHOT™ TAN Nails and Accessories
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB, HWC
Dated: February 24, 2010
Received: February 25, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K092748

Device Name: SURESHOT™ TAN Nails and Accessories

Indications for Use:

SURESHOT™ TAN Nails are indicated for fractures of the femur including 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; and for fixation of fractures that occur in and between the *proximal third* and *distal fourth* of the femur.

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SURESHOT™ TAN Nails and Accessories are for single use only.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092748