K123948

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Smith & Nephew, Inc.
Summary of Safety and Effectiveness
China Nails and Accessories

MAR 1 4 2013

Contact Person and Address:
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Cordova, TN 38016
(901) 399-5520

Date of Summary: December 19, 2012

Name of Device: China Nails and Accessories
Common Name: Intramedullary nail and accessories
Device Classification Name and Reference: 21CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories
Device Class: II
Panel Code: Orthopaedics/87 JDS

Predicate Devices:
Smith & Nephew TRIGEN InterTAN (K040212)
Smith & Nephew SURESHOT TAN and Accessories (K092748)
Smith & Nephew TRIGEN Low Profile Bone Screws (K111025)

Device Description:
Subject devices of this submission are China Nails and Accessories. The implant components included in the system are described in the following table.

China Nails and Accessories	Diameter	Length
Intramedullary Nails		
Universal Nails	9, 10, 11 mm	17 cm
Right and Left Hand Nails	9, 10, 11 mm	26 – 46 cm
Screws		
Lag Screws	8.6 mm	70 – 125 mm
Compression Screws	6.2 mm	65 – 120 mm
Nail Cap Set Screws	6.6 mm	0, 5, 10 mm
Distal Locking Screw	4.5 mm 5.0 mm	20 – 65 mm 20 – 110 mm

The implants are manufactured from titanium alloy (Ti-6Al-4V).

Intended Use:
The China Nails are indicated for simple long bone fractures; severely comminuted, spiral, long oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; bone lengthening and shortening; subtrochanteric fractures; ipsilateral femoral shaft/neck fractures; intertrochanteric fractures; and intracapsular fractures. The Smith & Nephew, Inc. China Nails are for single use only.

Substantial Equivalence Information:
The overall design, materials, and indications for use for the China Nails and Accessories are substantially equivalent to the commercially available predicate devices. China Nails and Accessories are similar to predicate devices as follows.

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- The indications for the China Nails and Accessories are the same as for the TRIGEN InterTAN.
- All three systems (China Nail, TRIGEN InterTAN and the SURESHOT TAN Nail) include an option to use the combination lag screw/compression screw design.
- All three systems (China Nail, TRIGEN InterTAN and the SURESHOT TAN Nail) are manufactured from titanium alloy.
- The distal screw holes for the China Nails and the SURESHOT TAN Nail Systems incorporate internal threads to aid in screw stability.
- The Locking Screw have the same design as the TRIGEN Low Profile Bone Screw cleared in K111025. The only difference is the surface anodization. The TRIGEN Low Profile Bone Screws are anodized while the China Nails Locking Screws are non-anodized.

Based on the comparisons, it is determined that the China Nails and Accessories are substantially equivalent to the predicate devices.

Technological Characteristics
Mechanical testing was conducted and the results were compared to testing conducted on predicate devices. Fatigue testing and a wear evaluation confirmed that the China Nails and Accessories are equivalent to the predicate devices and that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices

Conclusion
Based on the indications for use, similarities of designs, and the performance testing, it is determined that the China Nails and Accessories are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 14, 2013

Smith & Nephew, Incorporated
% Mr. Jason Sells
Group Manager, Regulatory Affairs
1450 Brooks Road
Memphis, Tennessee 38116

Re: K123948
Trade/Device Name: China Nails and Accessories
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDS
Dated: December 19, 2012
Received: December 21, 2012

Dear Mr. Sells:

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,

Erin D. Keith

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K123948

Device Name: China Nails and Accessories

Indications for Use:

The China Nails are indicated for simple long bone fractures; severely comminuted, spiral, long oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; bone lengthening and shortening; subtrochanteric fractures; ipsilateral femoral shaft/neck fractures; intertrochanteric fractures; and intracapsular fractures. The Smith & Nephew, Inc. China Nail is for single use only.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 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)

Casey E. Hanley, Ph.D.
Division of Orthopaedic Devices