K111667

DEC - 5 2011

3.0 510(k) Summary

Sponsor:
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6604

Date:
June 10, 2011

Contact:
Thomas N. Shea
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6809

Device Name:
Synthes Suprapatellar Insertion Instruments

Classification:
Class II, §888.3030 – Single / multiple component metallic bone fixation appliance and accessories.
Product Code: JDS (Nail, Fixation, Bone)

Predicate Devices:
Synthes (USA) Tibial Nail System EX (K040762).
Smith & Nephew TriGen® Meta-Nail Retrograde Femoral and Tibial Nail System (K061019).

Device Description:
The Synthes (USA) Suprapatellar Insertion Instruments consist of aiming arms, protection sleeves, trocars, and accessory instruments which are intended to facilitate the surgical approach for the insertion of intramedullary nail implants of the Synthes Tibial Nail System EX.

Indications for Use:
The Synthes Suprapatellar Insertion Instruments are part of the Synthes Tibial Nail System EX. The Synthes Tibial Nail System EX is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non-unions.

Substantial Equivalence:
Information presented in this premarket notification supports that there are no effects of the described modification on the safety and effectiveness of the predicate Synthes Tibial Nail System EX (K040762).The modification does not affect the predicate system's indications for use, design of intramedullary implants, fundamental technology and or implant material composition.

In vitro studies under simulated use, biocompatility testing of specific instrument components composed of non-standardized materials, as dimensional and tolerance based analyses were conducted and the results support the conlusion that there are no effects of the modification subject to this premarket notification on the safety and effectiveness of the Synthes Tibial Nail System EX.

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

Synthes (USA)
% Mr. Christopher Hack
1301 Goshen Parkway
West Chester, Pennsylvania 19380

DEC - 5 2011

Re: K111667
Trade/Device Name: Synthes Suprapatellar Insertion Instruments
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: October 26, 2011
Received: October 27, 2011

Dear Mr. Hack:

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

2.0 **Indications for Use**

510(k) Number (if known): K111667

Device Name: Synthes Suprapatellar Insertion Instruments

Indications for Use: The Synthes Suprapatellar Insertion Instruments are part of the Synthes Tibial Nail System EX. The Synthes Tibial Nail System EX is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non-unions.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (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 K111667