DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 26, 2016

Synthes (USA) Products, LLC
Christopher Medberry, Ph.D.
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K160167
Trade/Device Name: DePuy Synthes TFNA Augmentation System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, KTT
Dated: August 25, 2016
Received: August 26, 2016

Dear Dr. Medberry:

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 Parts 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160167

Device Name
DePuy Synthes TFNA Augmentation System

Indications for Use *(Describe)*
The Synthes Trochanteric Fixation Nail- Advanced (TFNA) System is intended for treatment of fractures in adults and adolescents (12-21) in which the growth plates have fused.
Specifically the system is indicated for:
• Stable and unstable pertrochanteric fractures
• Intertrochanteric fractures
• Basal neck fractures
• Combinations of pertrochanteric, intertrochanteric, and basal neck fractures
The Long Nail is additionally intended for treatment of fractures in adults and adolescents (12- 21) in which the growth plates have fused for the following indications:
• Subtrochanteric fractures
• Pertrochanteric fractures associated with shaft fractures
• Pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions
• Long Subtrochanteric fractures
• Proximal or distal non-unions, malunions and revisions

Both the short and long TFNA systems are additionally indicated for use with cleared polymethylmethacrylate (PMMA) bone cement that can be delivered through the fenestrated blade or screw via a cannula in skeletally mature adults with risk of cut-out or device instability due to poor bone quality.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Sponsor:	DePuy Synthes Christopher J. Medberry, Ph.D. 1301 Goshen Parkway West Chester, PA, 19380 Office: (610) 719-6806 Fax: (484) 356-9682
Date Prepared	September 23, 2016
DePuy Synthes TFNA Augmentation System	
Proprietary Name:	DePuy Synthes TFNA Augmentation System
Classification:	Classification: 888.3020, 888.3030 Product Code: HSB, KTT
Predicate Device:	Alta Dome and Plunger (K961213)
Reference Device:	DePuy Synthes TFNA System (K131548)
Device Description:	The DePuy Synthes TFNA Augmentation System consists of components to the predicate DePuy Synthes TFNA System with added perforations to the femoral head elements. The perforations enable the delivery of cleared PMMA bone cement(s) to be delivered through the helical blade/femoral neck screw in patients with poor bone quality and/or increased risk of fixation failure at the implant/bone interface. The materials of manufacture are the same as those used to manufacture the predicate TFNA hardware: Ti-15Mo (ASTM F-2066); Ti-6Al-7Nb (ASTM F1295); 40Co-20Cr-16Fe-15Ni-7Mo (ASTM F1058)
Indications for Use	The Synthes Trochanteric Fixation Nail- Advanced (TFNA) System is intended for treatment of fractures in adults and adolescents (12-21) in which the growth plates have fused. Specifically the system is indicated for: • Stable and unstable pertrochanteric fractures • Intertrochanteric fractures • Basal neck fractures • Combinations of pertrochanteric, intertrochanteric, and basal neck fractures The Long Nail is additionally intended for treatment of fractures in adults and adolescents (12- 21) in which the growth plates have fused for the following indications: • Subtrochanteric fractures • Pertrochanteric fractures associated with shaft fractures • Pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions

	• Long Subtrochanteric fractures • Proximal or distal non-unions, malunions and revisions Both the short and long TFNA systems are additionally indicated for use with cleared polymethylmethacrylate (PMMA) bone cement that can be delivered through the fenestrated blade or screw via a cannula in skeletally mature adults with risk of cut-out or device instability due to poor bone quality
Substantial Equivalence:	The proposed DePuy Synthes TFNA Augmentation System has similar intended use, indications, design characteristics, functionality, materials, and performance characteristics in comparison to the predicate devices. The following assessments have been completed to demonstrate substantial equivalence performance specifications: • Dynamic fatigue testing comparing the fenestrated and non-fenestrated head elements • Biomechanical evaluation of cut-out resistance Additional evaluations were conducted to confirm the ability of the fenestrated hardware to deliver bone cement in a controlled and predicable manner. • Flow patterns • Extraction validations