November 14, 2017

Synthes (USA) Products, LLC
Alexander Zwahlen
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K172157
Trade/Device Name: DePuy Synthes Femoral Recon Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 17, 2017
Received: October 19, 2017

Dear Mr. Zwahlen:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

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

Enclosure

DePuy Synthes

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)*
K172157

Device Name
DePuy Synthes Femoral Recon Nail System

Indications for Use *(Describe)*
The Femoral Recon Nail 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:
- Subtrochanteric fractures
- Ipsilateral neck/shaft fractures
- Femoral shaft fractures
- Impending pathologic fractures
- Malunions and nonunions

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.

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DePuy Synthes

6 510(k) Summary

Sponsor	DePuy Synthes Alexander Zwahlen 1301 Goshen Parkway West Chester, PA 19380 Phone: +41 32 720 41 04 Fax: +41 32 720 71 73
Date Prepared	July 17, 2017
Proprietary Name	DePuy Synthes Femoral Recon Nail System
Classification Name	Rod, Fixation, Intramedullary and Accessories
Classification	Class II Regulation Number: 21 CFR 888.3020 Product Code: HSB
Predicate Devices	Primary Predicate Device: Synthes Lateral Entry Femoral Nail System (K040336) Additional Predicate Device: Synthes Adolescent Lateral Entry Femoral Nail System (K070843) Smith & Nephew Trigen Trochanteric Antegrade Nail (K040462)
Device Description	The Femoral Recon Nail (FRN) System is comprised of intramedullary nailing implants designed to provide stabilization of femoral shaft and neck fractures as well as system specific insertion instruments. The Femoral Recon Nail System offers nailing implants in two different designs which enable a Piriformis Fossa (PF) and a Greater Trochanter (GT) entry point for the insertion of the nailing implant in the femur. The implants are manufactured from Titanium alloy, are provided in a range of dimensions and in Left and Right-oriented versions.
Indications for use	The Femoral Recon Nail 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: - Subtrochanteric fractures - Ipsilateral neck/shaft fractures - Femoral shaft fractures - Impending pathologic fractures - Malunions and nonunions

DePuy Synthes

Non-clinical Performance Data	Fatigue testing of constructs with standard locking and recon locking as well as an analytical evaluation has been performed to compare the subject device DePuy Synthes Femoral Recon Nail System to the primary predicate device Synthes Lateral Entry Femoral Nail System. This information supports that the mechanical performance of the subject device is at least equivalent to that of the predicate device. The devices also meet the specified endotoxin requirement of 20EU/device using the LAL test method.
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The proposed device has the same intended use as the predicate devices. The proposed device has similar indications for use, are similar in design, material, and fundamental technology as compared to the predicate devices. The mechanical testing and analytical evaluation included in this submission demonstrate that: • Any differences in technological characteristics of the predicate devices do not raise any new questions of safety and effectiveness. • The proposed devices are at least as safe and effective as the predicate devices. It is concluded that the information provided in this submission supports substantial equivalence.