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U.S. FOOD & DRUG ADMINISTRATION

Synthes (USA) Products, LLC
Pol Grebol
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380
USA

September 3, 2020

Re: K201336
Trade/Device Name: DePuy Synthes Tibial Nail Advanced System
DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDS, HWC
Dated: July 31, 2020
Received: August 3, 2020

Dear Pol Grebol:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael Owens
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201336

Device Name

DePuy Synthes Tibial Nail Advanced System
DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm

Indications for Use *(Describe)*

DePuy Synthes Tibial Nail Advanced System:

The Tibial Nail Advanced implants are intended for treatment of fractures in adults and adolescents (12-21) in which the growth plates have fused. Specifically, the implants are indicated for:

- Open and closed proximal and distal tibial fractures
- Open and closed tibial shaft fractures
- Tibial malunions and nonunions

DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm:

DePuy Synthes Locking Screws are used for the static and dynamic interlocking of femoral, humeral and tibial nails.

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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510(k) Summary

Sponsor	DePuy Synthes Pol Fort Grèbol 1301 Goshen Parkway West Chester, PA 19380 Phone: +41 76 371 52 69 Fax: +41 32 720 71 73
Date Prepared	May 18, 2020
Proprietary Name	DePuy Synthes Tibial Nail Advanced System DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm
Classification Product Code	JDS – Single/multiple component metallic bone fixation appliances and accessories HWC – Smooth or threaded metallic bone fixation fastener
Device Classification Name	Nail, Fixation, Bone Screw, Fixation, Bone
Regulation Number / Description	21 CFR § 888.3030 – Single/multiple component metallic bone fixation appliances and accessories 21 CFR § 888.3040 – Smooth or threaded metallic bone fixation fastener
Device Classification	Class II
Predicate Devices	Primary Predicate Device: Synthes (USA) Tibial Nail System Ex (K040762) Additional Predicate Device: Synthes 4.0 and 5.0 mm Locking Screws (K000089) Reference Device: DePuy Synthes Femoral Recon Nail System (K172157)
Device Description	<u>DePuy Synthes Tibial Nail Advanced System:</u> The DePuy Synthes Tibial Nail Advanced System is a system comprised of intramedullary nails, locking screws, end caps implants, as well as system-specific insertion instruments. The Tibial Nail Advanced System is intended to be used for temporary fixation and stabilization of tibia. This system enables three different surgical approaches for the insertion of the nailing implant in the tibia: suprapatellar, parapatellar, and infrapatellar. The implants are manufactured from titanium alloys and provided in a range of dimensions to match individual patient anatomy. The intramedullary nailing implants are cannulated and can be inserted over a reaming rod. The nailing implants are offered in a range of proximal and distal shaft

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	diameters and lengths to accommodate patient anatomy and surgical need related to the specific fracture patterns and locations. The nails will be manufactured from titanium alloy (Ti-6Al-4V) and polyetherketone (PEEK). <u>DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm:</u> The DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm have a diameter of 5 mm available in lengths ranging from 26 up to 120 mm and a diameter of 4 mm available in lengths ranging from 18 up to 80 mm. These implantable devices are fully threaded at the shaft and are self-tapping. The locking screws feature either a standard screw head or a low-profile screw head. The screws are made from titanium alloy (Ti-6Al-7Nb).
Indications for Use	<u>DePuy Synthes Tibial Nail Advanced System:</u> The Tibial Nail Advanced implants are intended for treatment of fractures in adults and adolescents (12-21) in which the growth plates have fused. Specifically, the implants are indicated for: • Open and closed proximal and distal tibial fractures • Open and closed tibial shaft fractures • Tibial malunions and nonunions <u>DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm:</u> DePuy Synthes Locking Screws are used for the static and dynamic interlocking of femoral, humeral and tibial nails.
Comparison of Technological Characteristics with the Predicate Device	<u>DePuy Synthes Tibial Nail Advanced System:</u> Device comparison demonstrated that the DePuy Synthes Tibial Nail Advanced System is substantially equivalent to the previsouly cleared Synthes (USA) Tibial Nail System Ex (K040762) regarding intended use, indications for use, technological characteristics (design features, material and performance) as well as operating principle. At a high level, the subject device and predicate devices are based on the following same technological elements: • Intramedulary nailing implants to provide fracture fixation and stabilization of the tibia • Nail and screw design (length, diameter, shape) • Nails, locking screws, and end caps manufactured from titanium alloys • Hole configurations in proximal and distal part of nail • Same locking options

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	<u>DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm:</u> Device comparison demonstrated that the DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm is substantially equivalent to the previsouly cleared Synthes 4.0 and 5.0 mm Locking Screws (K000089) regarding intended use, indications for use, technological characteristics (design features, material and performance) as well as operating principle. At a high level, the subject device and predicate devices are based on the following same technological elements: • Stabilization of intramedullary nail-bone construct • Design (length, diameter, thread profile) • Manufactured from titanium alloy • Used for proximally and distally locking of nail-bone construct
Non-clinical Performance Data	<u>DePuy Synthes Tibial Nail Advanced System:</u> The following non-clinical assessments were used to characterize the subject device as a system: • LAL testing to demonstrate that the subject device meets the 20 EU/device limit set forth in FDA guidance document "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," dated January 21, 2016, when sterilized utilizing gamma radiation • Biocompatibility assessment per FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," dated June 16, 2016 • Proximal and distal locking static torsion test of the construct according to ASTM F1264-16 A2.1.7 • MRI testing in accordance with standards ASTM F2052-14, ASTM F2213-06, ASTM F2182-11a, and ASTM F2119-07 Subject nailing implants were also evaluated against Synthes (USA) Tibial Nail System Ex (K040762): • Static 4-point bending test of the nail shaft according to ASTM F1264-16 A1 • Torsion testing of the nail shaft according to ASTM F1264-16 A2 • Dynamic 4-point bending test of the nail shaft according to ASTM-16 A3 <u>DePuy Synthes Locking Screws for Medullary Nails, 4.0 and 5.0 mm:</u> Subject locking screws were also evaluated against Synthes 4.0 and 5.0mm Locking Screws (K000089): • Engineering analysis on static and cyclic 3-point bending of the locking screws according to ASTM F1264-16 A4

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	• Torsional properties of the locking screws according to ASTM F543-17 A1 • Driving torque of the locking screws according to ASTM F543-17 A2 • Driving torque and axial push out strength of the locking screws according to ASTM F543-17 A2 and A3 • Self-tapping performance of the locking screws according to ASTM F543-17 A4 This information supports that the performance of the subject device is substantially equivalent to that of the predicate device.
Clinical Performance Data	Clinical performance data was not deemed necessary for the determination of substantial equivalence.
Substantial Equivalence	The proposed devices have the same intended use their predicate devices. Additionally, the devices have similar indications for use, design principles, materials, and fundamental technology as compared to the predicate devices. The 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
Conclusion	In conclusion, the results of non-clinical performance data demonstrate that the subject device is substantially equivalent with the predicate devices.