Synthes (USA) Products, LLC
Keith Knapp
RA Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380
USA

September 23, 2020

Re: K201346
Trade/Device Name: DePuy Synthes Retrograde Femoral Nail Advanced System, DePuy Synthes Locking Screws for Medullary Nails, 5.0 mm
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: August 20, 2020
Received: August 24, 2020

Dear Keith Knapp:

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)*
K201346

Device Name
DePuy Synthes Retrograde Femoral Nail Advanced System
DePuy Synthes Locking Screws for Medullary Nails, 5.0 mm

Indications for Use *(Describe)*
The DePuy Synthes Retrograde Femoral Nail Advanced System is intended to stabilize fractures of the distal femur and the femoral shaft, including:
- Supracondylar fractures, including those with intra-articular extension
- Combination of ipsilateral condylar and diaphyseal fractures
- Ipsilateral femur/tibia fractures
- Femoral fractures in multiple trauma patients
- Periprosthetic fractures
- Fractures in the morbidly obese
- Fractures in osteoporotic bone
- Impending pathologic fractures
- Malunions and nonunions

The DePuy Synthes Locking Screws for Medullary Nails, 5.0 mm are indicated 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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5. 510(k) Summary

Sponsor	DePuy Synthes Keith Knapp 1301 Goshen Parkway West Chester, PA 19380 Phone: +1-610-719-5942
Date Prepared	May 19, 2020
Proprietary Name	DePuy Synthes Retrograde Femoral Nail Advanced System DePuy Synthes Locking Screws for Medullary Nails, 5.0 mm
Device Common Name	Rod, Fixation, Intramedullary And Accessories Screw, Fixation, Bone
Classification Name	Intramedullary fixation rod. Smooth or threaded metallic bone fixation fastener.
Classification	Class II Regulation Number: 21 CFR 888.3020 & 888.3040 Product Code: HSB, HWC
Predicate Devices	Primary Predicate Devices: Synthes Retrograde/Antegrade Femoral Nail (K033618) Secondary Predicate Devices: Synthes 4.0 and 5.0mm Locking Screws (K000089)
Device Description	The proposed Retrograde Femoral Nail Advanced System is being developed to address challenges associated with treating distal femur fractures with intramedullary nails. The system is modular in nature, incorporating several components to allow for the treatment of a variety of fracture patterns and in the presence of previously implanted devices such as the femoral components of a total knee arthroplasty (periprosthetic). The nailing implants are available in two different bends which enable standard and periprosthetic entry points for the insertion of the nailing implant in the femur. The implants in this submission are manufactured from titanium alloys, stainless steel and polyethylene and are provided in a range of dimensions. The DePuy Synthes Locking Screws for Medullary Nails, 5.0 mm feature a retaining screw head recess, additional shorter, rounded cutting flutes the ability to drive under power. The screws feature either a standard screw head or a low-profile screw head and are available with standard washers and nuts.

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Indications for use	The Retrograde Femoral Nail Advanced System is indicated to stabilize fractures of the distal femur and femoral shaft, including: - Supracondylar fractures, including those with intraarticular extension - Combination of ipsilateral condylar and diaphyseal fractures - Ipsilateral femur/tibia fractures - Femoral fractures in multiple trauma patients - Periprosthetic fractures - Fractures in the morbidly obese - Fractures in osteoporotic bone - Impending pathologic fractures - Malunions and non-unions The DePuy Synthes Locking Screws for Medullary Nails, 5.0 mm are indicated for the static and dynamic interlocking of femoral, humeral and tibial nails.
Non-clinical Performance Data	The following analyses were conducted for the Retrograde Femoral Nail Advanced System • Static Bend according to ASTM F1264 • Static Torsion according to ASTM F1264 • Dynamic Bend according to ASTM F1264 • Mechanical Static Construct • Poly Inlay Screw Pull Out Test and Debris Evaluation The following analyses were conducted for the DePuy Synthes Locking Screws for Medullary Nails, 5.0 • Torsional Properties according to ASTM F543 • Driving Torque & Axial Pushout according to ASTM F543 • Driving Torque according to ASTM F543 • Self-tapping Performance according to ASTM F543 • Finite Element Analysis for 3-Point Bending according to ASTM 1264 Other Additional Analysis: • Endotoxin Testing was performed according to AAMI ST72 • MRI Conditional analysis has been performed to establish MR Conditional parameters for the subject implants however DePuy Synthes is choosing not to release these devices with MR Conditional labeling at this time
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The proposed subject devices have the same intended uses as the predicate devices. The proposed subject devices share similar or the same indications, are similar in design, material, and fundamental technology with the identified predicate devices.

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	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 In conclusion, the results of non-clinical performance data demonstrate that the subject device is substantially equivalent with the predicate devices.