December 26, 2018

DePuy Synthes
Elizabeth Jacobs
Regulatory Affairs Project Leader
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K182783
Trade/Device Name: see page 3, List of Cleared Devices in K182783
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HSB, HTY, JDS, JDW, KTT, LXT
Dated: September 28, 2018
Received: October 1, 2018

Dear Elizabeth Jacobs:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Shumaya Ali -S

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

Enclosure:
List of Cleared Devices in K182783

List of Cleared Devices in K182783

1. DePuy Synthes Trochanter Stabilization Plate for DHS - MR Conditional
2. Modification to DePuy Synthes Trochanter Stabilization Plate (TSP) for DHS (Line Extension) – MR Conditional
3. DePuy Synthes Proximal Humeral Nail - MR Conditional
4. DePuy Synthes Trochanteric Fixation Nail (TFN) System - MR Conditional
5. DePuy Synthes Retrograde/Antegrade Femoral Nail System - MR Conditional
6. DePuy Synthes Lateral Entry Femoral Nail System - MR Conditional
7. DePuy Synthes Elastic Intramedullary Nail (EIN) System (Line Extension) – MR Conditional
8. DePuy Synthes LCP Dynamic Helical Hip System - MR Conditional
9. DePuy Synthes Hindfoot Arthrodesis Nail System - MR Conditional
10. DePuy Synthes Universal Locking Trochanter Stabilization Plate - MR Conditional
11. DePuy Synthes Trochanteric Fixation Nail (TFN) System - MR Conditional
12. DePuy Synthes Adolescent Lateral Entry Femoral Nail System - MR Conditional
13. DePuy Synthes Olecranon Osteotomy Nailing (OleON) System - MR Conditional
14. DePuy Synthes Trochanteric Fixation Nail (TFN) Screw - MR Conditional
15. DePuy Synthes Set Screw for Ti Trochanteric Fixation Nail (TFN) – MR Conditional
16. DePuy Synthes Trochanteric Fixation Nail - Advanced (TFNA) System – MR Conditional
17. DePuy Synthes Universal Femoral Nail - MR Conditional
18. DePuy Synthes Universal Tibial Nail and the DePuy Synthes Unreamed Tibial Nail – MR Conditional
19. DePuy Synthes TI-6AL-7NB Unreamed Femoral Nail – MR Conditional
20. DePuy Synthes TI-6AL-7NB Unreamed Tibial Nail (URTN) – MR Conditional
21. Accessories to DePuy Synthes Titanium Alloy Unreamed Femoral Nail (URFN) – MR Conditional
22. DePuy Synthes Unreamed Humeral Nail (URHN) – MR Conditional
23. DePuy Synthes Cannulated Femoral Nail (CFN) – MR Conditional
24. DePuy Synthes Titanium Cannulated Tibial Nail (TI CTN) – MR Conditional
25. DePuy Synthes Proximal Femoral Nail (PFN) System – MR Conditional
26. DePuy Synthes Titanium Distal Femoral Nail (TI DFN) System – MR Conditional
27. DePuy Synthes Elastic Intramedullary Nail (EIN) System – MR Conditional
28. DePuy Synthes Spiral Blade for Humeral Nail (SBHN) – MR Conditional

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)*

K182783

Device Name
DePuy Synthes Trochanter Stabilization Plate for DHS - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Trochanter Stabilization Plate (TSP) for DHS is intended to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the DePuy Synthes Dynamic Hip Screw (DHS) plating system.

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)

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510(k) Number *(if known)*

K182783

Device Name
Modification to DePuy Synthes Trochanter Stabilization Plate (TSP) for DHS (Line Extension) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Trochanter Stabilization Plate (TSP) for the Dynamic Hip Screw System (DHS®) is intended to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the DHS® System.

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)

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K182783

Device Name

DePuy Synthes Proximal Humeral Nail - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Proximal Humeral Nail is intended for use in fractures of the proximal humerus.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Trochanteric Fixation Nail (TFN) System - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Trochanteric Fixation Nail (TFN) System is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for 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.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Retrograde/Antegrade Femoral Nail System - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Retrograde/Antegrade Femoral Nail System is intended to stabilize fractures of the distal femur and the femoral shaft, including:

- supracondylar fractures, including those with intra-articular extension;
- ipsilateral hip/shaft fractures;
- ipsilateral femur/tibia fractures;
- femoral fractures in multiple trauma patients;
- fractures proximal to total knee arthroplasty;
- fractures distal to a hip implant;
- fractures in the morbidly obese;
- fractures in osteoporotic bone, 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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Lateral Entry Femoral Nail System - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Lateral Entry Femoral Nail System is intended to stabilize femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions.

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)

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510(k) Number *(if known)*

K182783

Device Name

DePuy Synthes Elastic Intramedullary Nail (EIN) System (Line Extension) – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Elastic Intramedullary Nail (EIN) System (Line Extension) is indicated for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small-stature patients. This system is also intended to treat metaphyseal and epiphyseal fractures, such as radial neck fractures and is intended for fixation of small long bones, such as carpal and tarsal bones. In pediatric applications, the flexibility of the EIN allows it to be inserted at a point which avoids disruption to the bone growth plate.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes LCP Dynamic Helical Hip System - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Dynamic Helical Hip System, Additional Helix Blades is intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

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)

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K182783

Device Name

DePuy Synthes Hindfoot Arthrodesis Nail System - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Hindfoot Arthrodesis Nail System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include, but are not limited to Neuro-osteoarthropathy (Charcot's Foot), Avascular Necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, Osteoarthritis, Rheumatoid Arthritis, and Pseudoarthrosis.

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)

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K182783

Device Name
DePuy Synthes Universal Locking Trochanter Stabilization Plate - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Universal Locking Trochanter Stabilization Plate (ULTSP) for DHS or LCP DHHS is intented to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the Synthes Dynamic Hip Screw (DHS) or the LCP Dynamic Helical Hip System (DHHS) side plates with four or more holes.

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)

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K182783

Device Name
DePuy Synthes Trochanteric Fixation Nail (TFN) System - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Trochanteric Fixation Nail (TFN) System, Additional Helical Blades is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for 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.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Adolescent Lateral Entry Femoral Nail System - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Adolescent Lateral Entry Femoral Nail System will be intended to stabilize fractures of the femoral shaft, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions in adolescent and small stature adult patients.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Olecranon Osteotomy Nailing (OleON) System - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Olecranon Osteotomy Nailing (OleON) System is intended to treat olecranlon osteotomies as well as simple fractures of the olecranon.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Trochanteric Fixation Nail (TFN) Screw - MR Conditional

Indications for Use *(Describe)*

As part of the DePuy Synthes Trochanteric Fixation Nail (TFN) System, the DePuy Synthes Trochanteric Fixation Nail (TFN) Screw is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for 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.

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

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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)*

K182783

Device Name

DePuy Synthes Set Screw for Ti Trochanteric Fixation Nail (TFN) – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Set Screw for Ti Trochanteric Fixation Nail (TFN) is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures and combinations thereof. The long TFN is additionally indicated for 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.

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)

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See PRA Statement below.

510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Trochanteric Fixation Nail - Advanced (TFNA) System – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Trochanteric Fixation Nail - Advanced (TFNA) System is intended for treatment offractures 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

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)

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See PRA Statement below.

510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Universal Femoral Nail - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Universal Femoral Nail is intended for use in stabilizing fractures of the femur. More specifically, the primary intended use is stable midshaft (diaphyseal) femoral fracture and hypertrophic pseudarthrosis (non-union) or unstable femoral fracture stabilization.

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)

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510(k) Number *(if known)*

K182783

Device Name

DePuy Synthes Universal Tibial Nail and the DePuy Synthes Unreamed Tibial Nail – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Universal Tibial Nail and the DePuy Synthes Unreamed Tibial Nail are intended for use in stabilizing fractures of the tibia. More specifically, the primary intended use of the Universal Tibial Nail is stable diaphyseal fractures or long or rotationally-unstable diaphyseal fractures, including rotationally unstable proximal and distal diaphyseal fractures. For the Unreamed Tibial Nail, the specific intended uses are Grade I and II open tibial diaphyseal fractures; high energy, unstable, closed fracture patterns; comminuted fractures of tibias with small medullary canals; and certain pre- and postisthmic fractures.

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)

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See PRA Statement below.

510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes TI-6AL-7NB Unreamed Femoral Nail – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes TI-6AI-7NB Unreamed Femoral Nail is intended for use in stabilizing fractures of the femur. Specific Indications: Acute femoral diaphyseal fractures; post-isthmic femoral fractures; subtrochanteric femoral fractures.

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes TI-6AL-7NB Unreamed Tibial Nail (URTN) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes TI-6AL-7NB Unreamed Tibial Nail (URTN) is intended to stabilize fractures of the tibia. Specifically, it is intended for grade I and II open tibial diaphyseal fractures; high energy, unstable, closed fracture patterns; comminuted fractures of tibiae with small medullary canals; and certain pre- and post-isthmic fractures.

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)

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510(k) Number *(if known)*

K182783

Device Name
Accessories to DePuy Synthes Titanium Alloy Unreamed Femoral Nail (URFN) – MR Conditional

Indications for Use *(Describe)*
The accessories are intended for use with the DePuy Synthes Titanium Alloy Unreamed Femoral Nail (URFN), which is intended for use in stabilizing fractures of the femur. The Synthes Twisted Blade and 5.0 mm Shaft Screw, used with the Locking Sleeve and End Cap, are intended to transmit load between the bone and the URFN to prevent rotation and displacement of the nail/fracture when stabilizing subtrochanteric femoral fractures (short, long, reverse oblique and comminuted).

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Unreamed Humeral Nail (URHN) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Unreamed Humeral Nail (URHN) is intended to stabilize fractures of the humerus. It is specifically indicated for acute humeral shaft fractures, pathologic or impending pathologic fractures of the humeral shaft, and non- and mal unions of the humeral shaft.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Cannulated Femoral Nail (CFN) – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Cannulated Femoral Nail (CFN) is intended to stabilize fractures of the femur. Specifically, the primary intended use is acute femoral diaphyseal fractures, post-isthmic femoral fractures, subtrochanteric femoral fractures, non-unions and impending pathological fractures.

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)

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510(k) Number *(if known)*

K182783

Device Name

DePuy Synthes Titanium Cannulated Tibial Nail (TI CTN) – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Titanium Cannulated Tibial Nail (TI CTN) is intended to stabilize fractures of the tibia. Indications include, but are not limited to, open and closed tibial shaft fractures, certain pre- and post-isthmic fractures, tibial malunions and tibial non-unions.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Proximal Femoral Nail (PFN) System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Proximal Femoral Nail (PFN) System is intended to treat stable and unstable proximal femoral fractures including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures, and combinations of these fractures.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Titanium Distal Femoral Nail (TI DFN) System – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Titanium Diastal Femoral Nail (TI DFN) System is generally intended to stabilize fractures of the distal femur. Specifically, the Ti DFN is intended for supracondylar fractures (including those with intra-articular and/or extra-articular involvement), pathologic fractures, mal-unions, non-unions, ipsilateral hip/shaft fractures, ipsilateral femur/tibia fractures, fractures proximal to a total knee, fractures distal to a total hip, fractures in the multiply injured patient, fractures in the morbidly obese patient, and fractures in osteoporotic bane. The Ti DFN can be used in either reamed or non-reamed applications.

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)

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Elastic Intramedullary Nail (EIN) System – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Elastic Intramedullary Nail (EIN) System is intended for fixation of diaphyseal fractures of the long bones where the medullary canal is narrow or flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small-statured patients. In pediatric applications, the flexibility of the EIN allows it to be inserted at a point which avoids disruption to the bone growth plate.

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)

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Indications for Use

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510(k) Number *(if known)*

K182783

Device Name
DePuy Synthes Spiral Blade for Humeral Nail (SBHN) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Spiral Blade for Humeral Nail (SBHN) is intended to stabilize fractures of the humerus.

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)

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1. 510(k) Summary

Date Prepared: September 28, 2018

1.1. Submitter

Primary Contact:
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1.2. Device

Name of Device: DePuy Synthes Trochanter Stabilization Plate for DHS – MR Conditional

Classification Name(s): Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component, Metal Composite

Regulatory Class: Class II; 888.3030

Product Code(s): LXT

1.3. Predicate Device

K000972 SYNTHES (USA) TROCHANTER STABILIZATION PLATE FOR DHS

1.4. Device Description

The DePuy Synthes Trochanter Stabilization Plate for DHS is a component of the DePuy Synthes DHS System, which fits over the sideplate of the DHS. The spoon-shaped area of the TSP, which is proximal to the shaft, resides along the greater trochanter. Screw holes of the TSP shaft line up with the screw holes of the DHS plate to accept the 4.5 mm cortex screws used for fixation to the femoral shaft. Two screw slots accommodate the DHS lag screw and the anti-rotational screw located proximal to it. The DePuy Synthes Trochanter Stabilization Plates are provided both pre-sterilized by gamma radiation and nonsterile.

1.5. Indications for Use

The DePuy Synthes Trochanter Stabilization Plate (TSP) for DHS is intended to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the DePuy Synthes Dynamic Hip Screw (DHS) plating system.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Trochanter Stabilization Plate for DHS. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Trochanter Stabilization Plate for DHS in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: September 28, 2018

1.1. Submitter

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1.2. Device

Name of Device: Modification to DePuy Synthes Trochanter Stabilization Plate (TSP) for DHS (Line Extension) – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, N/A

1.3. Predicate Device

K002710 Modification to Synthes (USA) Trochanter Stabilization Plate (TSP) for DHS (Line Extension)

1.4. Device Description

The DePuy Synthes TSP line extension is a shorter length version of the currently marketed TSP Plating System. It is a component of the DePuy Synthes DHS System, which fits over the sideplate of the DHS. The spoon-shaped area of the TSP, which is proximal to the shaft, resides along the greater trochanter. Four (4) screw holes in the TSP shaft line up with the screw holes of the DHS plate to accept the 4.5 mm cortex screws used for fixation to the femoral shaft. Two screw slots accommodate the DHS lag screw and the anti-rotational screw located proximal to it. DePuy Synthes Trochanter Stabilization Plate is provided both pre-sterilized by gamma radiation and nonsterile.

1.5. Indications for Use

The DePuy Synthes Trochanter Stabilization Plate (TSP) for the Dynamic Hip Screw System (DHS®) is intended to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the DHS® System.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the Modification to Synthes (USA) Trochanter Stabilization Plate (TSP) for DHS (Line Extension). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the Modification to Synthes (USA) Trochanter Stabilization Plate (TSP) for DHS (Line Extension) in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: September 28, 2018

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Proximal Humeral Nail – MR Conditional

Classification Name(s): Nail, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): JDS, N/A

1.3. Predicate Device

K002729 Synthes (USA) Proximal Humeral Nail

1.4. Device Description

The DePuy Synthes Proximal Humeral Nail is an intramedullary rod that features a distal taper design. It is 150 mm in length and has holes in both the proximal and distal sections that accept locking screws.

1.5. Indications for Use

The DePuy Synthes Proximal Humeral Nail is intended for use in fractures of the proximal humerus.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Proximal Humeral Nail. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Proximal Humeral Nail in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Trochanteric Fixation Nail (TFN) System – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, HWC

1.3. Predicate Device

K011857 Synthes (USA) Trochanteric Fixation Nail (TFN) System

1.4. Device Description

The DePuy Synthes Trochanteric Fixation Nail (TFN) System consists of a cannulated intermedullary nail, a cannulated helical blade and cannulated nail end cap. The TFN Nail is anatomically contoured with a proximal diameter of 17 mm, tapering to a nominal diameter of 10, 11 or 12 mm. The proximal locking hole accommodates angles ranging from 125 - 135°. TFN nails are to be available in short lengths (170 - 235 mm) and long lengths (300 - 460 mm), with the long length nails available in right or left versions. The Trochanteric Fixation Nail accepts commercially available Synthes 4.9 mm Locking Bolts and/or 5.0 mm Locking Screws.

1.5. Indications for Use

The DePuy Synthes Trochanteric Fixation Nail (TFN) System is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for 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.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Trochanteric Fixation Nail (TFN) System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Trochanteric Fixation Nail (TFN) System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Retrograde/Antegrade Femoral Nail System – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, HWC

1.3. Predicate Device

K033618 Synthes (USA) Retrograde/Antegrade Femoral Nail System

1.4. Device Description

The DePuy Synthes Retrograde/Antegrade Femoral Nail System is composed of femoral nails, spiral blades and end caps. Depending on the length of the nail, the nail may be inserted from a retrograde approach or from either a retrograde or antegrade approach. Spiral blades, end caps and Synthes commercially available locking bolts and screws are used to secure the nail in the bone, preventing rotation and axial compression

1.5. Indications for Use

The DePuy Synthes Retrograde/Antegrade Femoral Nail System is intended to stabilize fractures of the distal femur and the femoral shaft, including:

- supracondylar fractures, including those with intra-articular extension;
- ipsilateral hip/shaft fractures;
- ipsilateral femur/tibia fractures;

- femoral fractures in multiple trauma patients;
- fractures proximal to total knee arthroplasty;
- fractures distal to a hip implant;
- fractures in the morbidly obese;
- fractures in osteoporotic bone, impending pathologic fractures;
- malunions and nonunions

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Retrograde/Antegrade Femoral Nail System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Retrograde/Antegrade Femoral Nail System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Lateral Entry Femoral Nail System – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K040336 Synthes (USA) Lateral Entry Femoral Nail System

1.4. Device Description

The DePuy Synthes Lateral Entry Femoral Nail System is composed of cannulated femoral nails, solid 6.5 mm recon locking screws and cannulated end caps. Recon locking screws, as well as Synthes commercially available 5.0 mm and 6.0 mm locking screws, are used to secure the nail in the bone.

1.5. Indications for Use

The DePuy Synthes Lateral Entry Femoral Nail System is intended to stabilize femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Lateral Entry Femoral Nail System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Lateral Entry Femoral Nail System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Elastic Intramedullary Nail (EIN) System (Line Extension) – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K042135 Synthes (USA) Elastic Intramedullary Nail (EIN) System (Line Extension)

1.4. Device Description

The DePuy Synthes Elastic Intramedullary Nail (EIN) System (Line Extension) consists of flexible intramedullary fixation devices that vary in diameters and lengths, which can be cut to size intraoperatively. The EIN has a curved tapered tip to facilitate insertion and manipulation. The EIN is manufactured from Titanium Alloy.

1.5. Indications for Use

The DePuy Synthes Elastic Intramedullary Nail (EIN) System (Line Extension) is indicated for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small-stature patients. This system is also intended to treat metaphyseal and epiphyseal fractures, such as radial neck fractures and is intended for fixation of small long bones, such as carpal and tarsal bones. In pediatric applications, the flexibility of the EIN allows it to be inserted at a point which avoids disruption to the bone growth plate.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Elastic Intramedullary Nail (EIN) System (Line Extension). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Elastic Intramedullary Nail (EIN) System (Line Extension) in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes LCP Dynamic Helical Hip System, Additional Helix Blades – MR Conditional

Classification Name(s): Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Regulatory Class: Class II; 888.3030

Product Code(s): KTT, N/A

1.3. Predicate Device

K042895 Synthes LCP Dynamic Helical Hip System, Additional Helix Blades

1.4. Device Description

The DePuy Synthes LCP Dynamic Helical Hip System, Additional Helix Blades is a plate and screw system that consists of a straight plate with an angled barrel that accepts a helical blade. Synthes Helical blades, ranging in lengths from 135 mm to 150 mm are to be added to this system.

1.5. Indications for Use

The DePuy Synthes LCP Dynamic Helical Hip System, Additional Helix Blades is intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes LCP Dynamic Helical Hip System, Additional Helix Blades. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes LCP Dynamic Helical Hip System, Additional Helix Blades in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Hindfoot Arthrodesis Nail System – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K051678 Synthes Hindfoot Arthrodesis Nail System

1.4. Device Description

The DePuy Synthes Hindfoot Arthrodesis Nail System is composed of titanium cannulated arthrodesis nails, 6.0 mm Locking Screws, and end caps. DePuy Synthes commercially available spiral blades, locking screws, and locking bolts are used to secure the nail in the bone, preventing rotation and axial compression.

1.5. Indications for Use

The DePuy Synthes Hindfoot Arthrodesis Nail System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include, but are not limited to Neuro-osteoarthropathy (Charcot's Foot), Avascular Necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, Osteoarthritis, Rheumatoid Arthritis, and Pseudoarthrosis.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Hindfoot Arthrodesis Nail System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Hindfoot Arthrodesis Nail System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Universal Locking Trochanter Stabilization Plate (ULTSP) – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, N/A

1.3. Predicate Device

K052677 Synthes Universal Locking Trochanter Stabilization Plate (ULTSP)

1.4. Device Description

The DePuy Synthes Universal Locking Trochanter Stabilization Plate (ULTSP) for DHS® and LCP DHHS fits over the sideplate of the DePuy Synthes DHS and LCP®DHHS. The ULTSP screw holes line up with the most proximal screw holes of the DHS and LCP DHHS sideplate and accept 4.5 mm cortex screws used for femoral shaft fixation. Slots accommodate both the DHS lag screw or the LCP DHHS Helix Blade and a parallel anti-rotational screw. The screw slot for the anti-rotational screw accepts a 6.5 mm cancellous bone screw or 6.5 mm, 7.0 mm or 7.3 mm cannulated screw. The proximal extension of the plate resides along the lateral side of the greater trochanter. The proximal locking holes of the ULTSP accept 3.5 mm locking screws and/or k-wires, cables, or sutures up to 2.0 mm in diameter.

1.5. Indications for Use

The DePuy Synthes Universal Locking Trochanter Stabilization Plate (ULTSP) for DHS or LCP DHHS is intented to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the Synthes Dynamic Hip Screw (DHS) or the LCP Dynamic Helical Hip System (DHHS) side plates with four or more holes.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Universal Locking Trochanter Stabilization Plate (ULTSP). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Universal Locking Trochanter Stabilization Plate (ULTSP) in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Trochanteric Fixation Nail (TFN) System, Additional Helical Blades – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, HWC

1.3. Predicate Device

K070294 Synthes Trochanteric Fixation Nail (TFN) System, Additional Helical Blades

1.4. Device Description

The DePuy Synthes Trochanteric Fixation Nail (TFN) System, Additional Helical Blades consists of a cannulated femoral nail, a cannulated helical blade and a cannulated nail end cap. DePuy Synthes Helical Blades will be available in three additional lengths, 75 mm, 125 mm, and 130 mm.

1.5. Indications for Use

The DePuy Synthes Trochanteric Fixation Nail (TFN) System, Additional Helical Blades is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for 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.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Trochanteric Fixation Nail (TFN) System, Additional Helical Blades. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Trochanteric Fixation Nail (TFN) System, Additional Helical Blades in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Adolescent Lateral Entry Femoral Nail System – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K070843 Synthes Adolescent Lateral Entry Femoral Nail System

1.4. Device Description

The DePuy Synthes Adolescent Lateral Entry Femoral Nail System is composed of cannulated femoral nails, solid 5.0 mm recon locking screws and cannulated end caps. Recon locking screws, as well as Synthes commercially available 4.0 mm locking screws, are used to secure the nail in the bone.

1.5. Indications for Use

The DePuy Synthes Adolescent Lateral Entry Femoral Nail System will be intended to stabilize fractures of the femoral shaft, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions in adolescent and small stature adult patients.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Adolescent Lateral Entry Femoral Nail System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Adolescent Lateral Entry Femoral Nail System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Olecranon Osteotomy Nailing System – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K073402 Synthes Olecranon Osteotomy Nailing System

1.4. Device Description

The DePuy Synthes Olecranon Osteotomy Nailing System consists of machined metallic olecranon nails, end caps and screws which are designed for use in fixation of fractures and osteotomies of the olecranon process of the ulna.

The DePuy Synthes Olecranon Osteotomy Nailing System offers a unique alternative to current techniques for olecranon fracture and Olecranon osteotomy fixation. The system allows for quick realignment of the olecranon fragment following procedures which are primary to the repair of the olecranon osteotomy.

1.5. Indications for Use

The DePuy Synthes Olecranon Osteotomy Nailing (OleON) System is intended to treat olecranlon osteotomies as well as simple fractures of the olecranon.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Olecranon Osteotomy Nailing System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Olecranon Osteotomy Nailing System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Trochanteric Fixation Nail (TFN) Screw – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, HWC

1.3. Predicate Device

K092646 Synthes (USA) Trochanteric Fixation Nail (TFN) Screw

1.4. Device Description

The DePuy Synthes Trochanteric Fixation Nail (TFN) Screw is a threaded component composed of titanium alloy which is intended for use with DePuy Synthes Trochanteric Fixation Nails to provide stabilization of fractures of the proximal femur.

1.5. Indications for Use

As part of the DePuy Synthes Trochanteric Fixation Nail (TFN) System, the DePuy Synthes Trochanteric Fixation Nail (TFN) Screw is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for 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.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Trochanteric Fixation Nail (TFN) Screw. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Trochanteric Fixation Nail (TFN) Screw in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: September 28, 2018

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Set Screw for Ti Trochanteric Fixation Nail (TFN) – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, HWC

1.3. Predicate Device

K120083 Set Screw for Ti Trochanteric Fixation Nail (TFN)

1.4. Device Description

The DePuy Synthes Set Screw for Ti Trochanteric Fixation Nail (TFN) is an additional offering for use with the existing TEN System. The Set Screw prevents sliding and rotation of the head element (TFN Screw or helical blade) within the nail for fixation of proximal femur fractures.

1.5. Indications for Use

The DePuy Synthes Set Screw for Ti Trochanteric Fixation Nail (TFN) is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures and combinations thereof. The long TFN is additionally indicated for 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.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Set Screw For Ti Trochanteric Fixation Nail (TFN). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Set Screw For Ti Trochanteric Fixation Nail (TFN) in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Trochanteric Fixation Nail - Advanced (TFNA) System – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K131548 Synthes Trochanteric Fixation Nail - Advanced System

1.4. Device Description

The DePuy Synthes Trochanteric Fixation Nail - Advanced (TFNA) System consists of cephalomedullary nails, screw and blade head elements, end caps, distal locking options, and device specific insertion/removal instruments.

1.5. Indications for Use

The DePuy 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

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Trochanteric Fixation Nail - Advanced (TFNA) System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Trochanteric Fixation Nail - Advanced (TFNA) System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Universal Femoral Nail – MR Conditional

Classification Name(s): Nail, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): JDS, N/A

1.3. Predicate Device

K914371 Universal Femoral Nail

1.4. Device Description

The DePuy Synthes Universal Femoral Nail, regardless of whether Synthes provides sterile or non-sterile for subsequent sterilization by the user institution, is manufactured from 316L stainless steel seamless tubing with a nominal thickness of 1.25 mm. It is available in sizes ranging from 10 mm to 19 mm in diameter and 300 mm to 480 mm in length. The nail has a gradual bow with a radius of curvature of 1.5 m which closely resembles the average femur. The nail is slotted along its anterior length to facilitate implantation and explantation. The nail has two proximal and two distal 5.0 mm diameter transverse locking holes which accept locking screws.

1.5. Indications for Use

The DePuy Synthes Universal Femoral Nail is intended for use in stabilizing fractures of the femur. More specifically, the primary intended use is stable midshaft (diaphyseal) femoral fracture and hypertrophic pseudarthrosis (non-union) or unstable femoral fracture stabilization.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Universal Femoral Nail. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Universal Femoral Nail in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Universal Tibial Nail and the DePuy Synthes Unreamed Tibial Nail – MR Conditional

Classification Name(s): Nail, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): JDS, N/A

1.3. Predicate Device

K914453 Universal Tibial Nail and Unreamed Tibial Nail

1.4. Device Description

The DePuy Synthes Universal Tibial Nail is made from stainless steel tubing with a nominal wall thickness of 1.25 mm. It is available as 10 mm, 11 mm, 12 mm, 13 mm, and 14 mm in diameter and lengths ranging from 240 mm to 360 mm in length (in 15 mm increments), and 360 mm to 420 mm in length (in 20 mm increments). The nail has a bend with an angulation of 11°, which facilitates insertion in the average tibia. The nail is slotted along its posterior length for flexibility during implantation and explantation. The nail has two 5.0 mm diameter locking holes and a slot proximally, and three 5.0 mm diameter locking holes distally which accept locking screws.

The DePuy Synthes Unreamed Tibial Nail is available in sizes ranging from 8 mm to 9 mm in diameter and in 15 mm increments from 255 mm to 360 mm in length, and 20 mm increments

from 360 mm to 420 mm in length. The nail has a bend with an angulation of 9° which facilitates insertion in the average tibia. The nail has two 4.0 mm diameter locking holes proximally and two locking holes distally which accept locking screws.

1.5. Indications for Use

The DePuy Synthes Universal Tibial Nail and the DePuy Synthes Unreamed Tibial Nail are intended for use in stabilizing fractures of the tibia. More specifically, the primary intended use of the Universal Tibial Nail is stable diaphyseal fractures or long or rotationally-unstable diaphyseal fractures, including rotationally unstable proximal and distal diaphyseal fractures. For the Unreamed Tibial Nail, the specific intended uses are Grade I and II open tibial diaphyseal fractures; high energy, unstable, closed fracture patterns; comminuted fractures of tibias with small medullary canals; and certain pre- and postisthmic fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Universal Tibial Nail and the DePuy Synthes Unreamed Tibial Nail. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Universal Tibial Nail and the DePuy Synthes Unreamed Tibial Nail in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes TI-6AL-7NB Unreamed Femoral Nail – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K923580 Synthes TI-6AL-7NB Unreamed Femoral Nail

1.4. Device Description

The DePuy Synthes TI-6Al-7NB Unreamed Femoral Nail is intended to stabilize fractures of the femur. Specifically, the primary intended use is acute femoral diaphyseal fractures, post-isthmic femoral fractures and subtrochanteric femoral fractures.

1.5. Indications for Use

The DePuy Synthes TI-6Al-7NB Unreamed Femoral Nail is intended for use in stabilizing fractures of the femur. Specific Indications: Acute femoral diaphyseal fractures; post-isthmic femoral fractures; subtrochanteric femoral fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes TI-6AI-7NB Unreamed Femoral Nail. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes TI-6AI-7NB Unreamed Femoral Nail in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes TI-6AL-7NB Unreamed Tibial Nail (URTN) – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K932330 TI-6AL-7NB Unreamed Tibial Nail (URTN)

1.4. Device Description

The DePuy Synthes TI-6AL-7NB Unreamed Tibial Nail (URTN) is intended for use in stabilizing fractures of the tibia. It is available in diameters of 8 mm – 9 mm, and lengths from 255 mm to 420 mm. The nail has a proximal angulation of 9° in the sagittal plane; it allows for interlocking with locking bolts.

1.5. Indications for Use

The DePuy Synthes TI-6AL-7NB Unreamed Tibial Nail (URTN) is intended to stabilize fractures of the tibia. Specifically, it is intended for grade I and II open tibial diaphyseal fractures; high energy, unstable, closed fracture patterns; comminuted fractures of tibiae with small medullary canals; and certain pre- and post-isthmic fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes TI-6AL-7NB Unreamed Tibial Nail (URTN). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes TI-6AL-7NB Unreamed Tibial Nail (URTN) in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: October 26, 2018

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1.2. Device

Name of Device: Accessories to DePuy Synthes Titanium Alloy Unreamed Femoral Nail (URFN) – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K932593 Accessories to Titanium Alloy Unreamed Femoral Nail (URFN)

1.4. Device Description

The Accessories to DePuy Synthes Titanium Alloy Unreamed Femoral Nail (URFN) are compared to Synthes 4.9 mm Locking Bolt. The accessories include: DePuy Synthes twisted blade, 5.0 mm shaft screw, locking sleeve, and end cap. They are available in a variety of lengths.

1.5. Indications for Use

The accessories are intended for use with the DePuy Synthes Titanium Alloy Unreamed Femoral Nail (URFN), which is intended for use in stabilizing fractures of the femur. The Synthes Twisted Blade and 5.0 mm Shaft Screw, used with the Locking Sleeve and End Cap, are intended to transmit load between the bone and the URFN to prevent rotation and displacement of the nail/fracture when stabilizing subtrochanteric femoral fractures (short, long, reverse oblique and comminuted).

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the Accessories to DePuy Synthes Titanium Alloy Unreamed Femoral Nail (URFN). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the Accessories to DePuy Synthes Titanium Alloy Unreamed Femoral Nail (URFN) in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: September 28, 2018

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Unreamed Humeral Nail (URHN) – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, N/A

1.3. Predicate Device

K933518 Synthes Unreamed Humeral Nail (URHN)

1.4. Device Description

The DePuy Synthes Unreamed Humeral Nail (URHN) has a 5° bend positioned 55 mm from the proximal end, and is available in lengths ranging from 180 mm to 360 mm in 20 mm increments. The nail is available in three diameters: 7.5 mm, 8.5 mm, and 9.5 mm. The nail has three proximal locking holes, and two distal locking holes oriented 90° to each other. All of the locking holes accept 4.0 mm self-tapping cancellous screws or 3.9 mm locking bolts. A cap screw threads into the proximal end of the nail.

1.5. Indications for Use

The DePuy Synthes Unreamed Humeral Nail (URHN) is intended to stabilize fractures of the humerus. It is specifically indicated for acute humeral shaft fractures, pathologic or impending pathologic fractures of the humeral shaft, and non- and mal unions of the humeral shaft.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Unreamed Humeral Nail (URHN). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Unreamed Humeral Nail (URHN) in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Cannulated Femoral Nail (CFN) – MR Conditional

Classification Name(s): Rod, Fixation, Intramedullary And Accessories

Regulatory Class: Class II; 888.3020

Product Code(s): HSB, JDS

1.3. Predicate Device

K954856 Cannulated Femoral Nail

1.4. Device Description

The DePuy Synthes Cannulated Femoral Nail (CFN) is a cannulated, locking intramedullary fixation device. The nail is available in diameters ranging from 10 to 15 mm, and lengths ranging from 300 mm to 480 mm. Each nail has the same proximal design, and then tapers (10 - 12 mm) or expands (13 - 15 mm) to the nominal diameter. The nail has a radius of curvature of 1.5 meters. The CFN has four 5 mm holes (two proximal and two distal) to allow interlocking with 4.9 mm Locking Bolts. The most proximal locking hole is elongated to allow for dynamization (compression of bone fragments) of the fracture, if desired.

1.5. Indications for Use

The DePuy Synthes Cannulated Femoral Nail (CFN) is intended to stabilize fractures of the femur. Specifically, the primary intended use is acute femoral diaphyseal fractures, post-isthmic femoral fractures, subtrochanteric femoral fractures, non-unions and impending pathological fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Cannulated Femoral Nail (CFN). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Cannulated Femoral Nail (CFN)in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Titanium Cannulated Tibial Nail (TI CTN) – MR Conditional

Classification Name(s): Nail, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): JDS, N/A

1.3. Predicate Device

K962047 Titanium Cannulated Tibial Nail (TI CTN)

1.4. Device Description

The DePuy Synthes Titanium Cannulated Tibial Nail (TI CTN) is available in sizes ranging from 11 mm to 14 mm in diameter and from 255 mm to 420 mm in length. The nail is a cannulated tube with a 9° bend in the sagittal plane which facilitates insertion into the tibia. There are four locking holes proximally and there are three locking holes distally. All of the locking holes accept 4.9 mm Titanium Locking Bolts.

1.5. Indications for Use

The DePuy Synthes Titanium Cannulated Tibial Nail (TI CTN) is intended to stabilize fractures of the tibia. Indications include, but are not limited to, open and closed tibial shaft fractures, certain pre- and post-isthmic fractures, tibial malunions and tibial non-unions.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Titanium Cannulated Tibial Nail (TI CTN). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Titanium Cannulated Tibial Nail (TI CTN) in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Proximal Femoral Nail (PFN) System – MR Conditional

Classification Name(s): Pin, Fixation, Threaded

Regulatory Class: Class II; 888.3040

Product Code(s): JDW, JDS

1.3. Predicate Device

K970097 Proximal Femoral Nail (PFN) System

1.4. Device Description

The DePuy Synthes Proximal Femoral Nail (PFN) System is an intramedullary nail which utilizes a weight bearing dynamic femoral neck screw and an anti-rotational parallel hip pin. Distal interlocking is performed with an aiming arm and can be either static or dynamic. The following components make up the PFN system: proximal femoral nails, hip pins, femoral neck screws, 4.9 mm locking bolts, and 17 mm end caps.

1.5. Indications for Use

The DePuy Synthes Proximal Femoral Nail (PFN) System is intended to treat stable and unstable proximal femoral fractures including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures, and combinations of these fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Proximal Femoral Nail (PFN) System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Proximal Femoral Nail (PFN) System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Titanium Distal Femoral Nail (TI DFN) System – MR Conditional

Classification Name(s): Pin, Fixation, Smooth

Regulatory Class: Class II; 888.3040

Product Code(s): HTY, N/A

1.3. Predicate Device

K970733 Synthes Titanium Distal Femoral Nail (TI DFN) System

1.4. Device Description

The DePuy Synthes Titanium Distal Femoral Nail (TI DFN) System is a cannulated and solid locking intramedullary fixation device. The following components make up the DFN system: Transverse Locking Nails, 6.0 mm Ti Locking Screws, 4.9 mrn Ti Locking Bolts, and End Caps.

1.5. Indications for Use

The DePuy Synthes Titanium Distal Femoral Nail (TI DFN) System is generally intended to stabilize fractures of the distal femur. Specifically, the Ti DFN is intended for supracondylar fractures (including those with intra-articular and/or extra-articular involvement), pathologic fractures, mal-unions, non-unions, ipsilateral hip/shaft fractures, ipsilateral femur/tibia fractures, fractures proximal to a total knee, fractures distal to a total hip, fractures in the multiply injured patient, fractures in the morbidly obese patient, and fractures in osteoporotic bane. The Ti DFN can be used in either reamed or non-reamed applications.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Titanium Distal Femoral Nail (TI DFN) System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Titanium Distal Femoral Nail (TI DFN) System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: September 28, 2018

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Elastic Intramedullary Nail (EIN) System – MR Conditional

Classification Name(s): Pin, Fixation, Smooth

Regulatory Class: Class II; 888.3040

Product Code(s): HTY, N/A

1.3. Predicate Device

K971783 Synthes Elastic Intramedullary Nail (EIN) System

1.4. Device Description

The DePuy Synthes Elastic Intramedullary Nail (EIN) System is intended for fixation of diaphyseal fractures of the long bones where the medullary canal is narrow or flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small-statured patients. In pediatric applications, the flexibility of the EIN allows it to be inserted at a point which avoids disruption to the bone growth plate.

1.5. Indications for Use

The DePuy Synthes Elastic Intramedullary Nail (EIN) System is intended for fixation of diaphyseal fractures of the long bones where the medullary canal is narrow or flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small-statured patients. In pediatric applications, the flexibility of the EIN allows it to be inserted at a point which avoids disruption to the bone growth plate.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Elastic Intramedullary Nail (EIN) System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Elastic Intramedullary Nail (EIN) System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: September 28, 2018

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1.2. Device

Name of Device: DePuy Synthes Spiral Blade for Humeral Nail (SBHN) – MR Conditional

Classification Name(s): Nail, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): JDS, N/A

1.3. Predicate Device

K992348 Synthes Spiral Blade for Humeral Nail (SBHN)

1.4. Device Description

The DePuy Synthes Spiral Blade for Humeral Nail (SBHN) is a component of DePuy Synthes Unreamed Humeral Nail System. The DePuy Synthes Spiral Blade is used in conjunction with the DePuy Synthes Unreamed Humeral Nail to stabilize fractures of the humerus. The SBHN has a 3.9 mm core diameter, a 10.5 mm blade width with nail slots that are 12 mm wide, has suture holes located around periphery of blade head, and is available in lengths ranging from 34 mm to 54 mm. A Locking End Cap is used to lock the Spiral Blade in place. The Locking End Cap has a 5 mm extension and a 3.5 mm hex drive.

1.5. Indications for Use

The DePuy Synthes Spiral Blade for Humeral Nail (SBHN) is intended to stabilize fractures of the humerus.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Spiral Blade for Humeral Nail (SBHN). The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Spiral Blade for Humeral Nail (SBHN) in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.