November 26, 2019

Synthes (USA) Products LLC / DePuy Orthopaedics Inc.
Keith Knapp
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K192745
Trade/Device Name: DePuy Synthes Trauma Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HTY, HWC, JDW, HTN, NDG, JDS, KTT
Dated: September 27, 2019
Received: September 30, 2019

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,

Shumaya Ali, M.P.H.
Acting Assistant Director
DHT6A: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
List of cleared devices in K192745

List of cleared devices in K192745

1. DePuy Synthes Locking Condylar Plate (LCP) System – MR Conditional
2. DePuy Synthes Sacral Bar System – MR Conditional
3. DePuy Synthes Spiked Washer – MR Conditional
4. DePuy Synthes 4.0 mm Titanium (TI) Locking Screws – MR Conditional
5. DePuy Synthes 5.0/7.3 mm Cannulated Locking Screws – MR Conditional
6. DePuy Synthes Peri-prosthetic Screws – MR Conditional
7. DePuy Synthes 3.5 mm Conical Screws – MR Conditional
8. DePuy Synthes Spherical Washers – MR Conditional
9. DePuy Synthes 6.5 mm Cancellous Screws – MR Conditional
10. DePuy Synthes 6.5 mm Midfoot Fusion Bolt – MR Conditional
11. DePuy Synthes Cortical Screws – MR Conditional
12. DePuy Synthes Cortex Screws (4.0 mm and 4.5 mm), DePuy Synthes Cannulated Screws (2.4 mm, 3.5 mm, 4.0 mm, 4.5 mm, 6.5 mm, 7.0 mm, and 7.3 mm), DePuy Synthes Headless Compression Screws (1.5 mm and 2.4 mm), DePuy Synthes Headless Compression Screws (3.0 mm and 4.5 mm), DePuy Synthes Headless Compression Screws (6.5 mm) – MR Conditional
13. DePuy Synthes 2.0 mm Quick Insertion Screws – MR Conditional
14. DePuy Synthes Anatomical Locking Plate System (ALPS) – MR Conditional
15. DePuy Synthes Sterile 3.0 mm Cannulated Screw and Threaded Washer – MR Conditional
16. DePuy Synthes Cannulated Angle Blade Plate (CAEP) System – MR Conditional

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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)*
K192745

Device Name
DePuy Synthes Locking Condylar Plate (LCP) System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Locking Condylar Plate (LCP) System is intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar fractures, fractures in normal or osteopenic bone, and 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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K192745

Device Name

DePuy Synthes Sacral Bar System – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Sacral Bar System is intended for fixation of fractures of the posterior pelvis, in areas of the posterior superior iliac spine and posterior inferior iliac spine, for sacral fractures and fracture-dislocations of the sacro-iliac joint.

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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Device Name
DePuy Synthes Spiked Washer – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Spiked Washer is intended for use in ligament reattachment or fixation, specifically re-adaptation of torn or avulsed ligaments.

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)*
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Device Name
DePuy Synthes 4.0 mm Titanium (TI) Locking Screws – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 4.0 mm Titanium Locking Screws are intended to be used with existing DePuy Synthes LCP® plating systems for the fixation of various long bones, such as the humerus, femur and tibia.

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)*
K192745

Device Name
DePuy Synthes 5.0/7.3 mm Cannulated Locking Screws – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 5.0/7.3 mm Cannulated Locking Screws are intended to be used with existing DePuy Synthes LCP® plating systems for the fixation of various long bones, such as the femur.

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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Device Name
DePuy Synthes Peri-prosthetic Screws – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Peri-Prosthetic Screws are intended for fixation of various long bones, such as the humerus, femur and tibia, in conjunction with DePuy Synthes Locking Plates that accept 4.0/5.0 mm locking screws. They are also for use in fixation of periprosthetic fractures, osteopenic bone, and fixation of nonunions or 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)*

K192745

Device Name
DePuy Synthes 3.5 mm Conical Screws – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm Conical Screws are intended to be used with existing DePuy Synthes LCP plating systems for fixation and interfragmentary compression of various bones, such as the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia and fibula, particularly in osteopenic bone.

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)*
K192745

Device Name
DePuy Synthes Spherical Washers – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Spherical Washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of large (long) bone and bone fragments.

In addition, the Spherical Washers are intended to prevent the projection of the screw head, when the screw must be inserted at an acute angle (e.g., in ankle arthrodesis).

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)*
K192745

Device Name
DePuy Synthes 6.5 mm Cancellous Screws – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes 6.5 mm Cancellous Screws are intended for use in hindfoot and midfoot fusions, subtalar fusions, calcaneal osteotomies, midfoot reconstruction, and ankle arthrodeses.

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)*

K192745

Device Name
DePuy Synthes 6.5 mm Midfoot Fusion Bolt – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes 6.5 mm Midfoot Fusion Bolt is indicated for fracture fixation, osteotomies, nonunions, and fusions of large bones in the foot and ankle.

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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K192745

Device Name
DePuy Synthes Cortical Screws – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes 1.0mm, 1.3mm, 1.5mm, 2.0mm, and 2.4mm Cortex Screws are intended for use in trauma procedures, reconstructive procedures, and general surgery of the hand, wrist, and other small bones and bone fragments in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 2. 7mm Cortex Screw is intended for fractures and osteotomies of small bones and bone fragments, including the foot, ankle, and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. The DePuy Synthes 2. 7mm Cortex Screw may also be used in fusion applications in adults and adolescents (12-21 years) when used with the DePuy Synthes 2.4mm/2.7mm Variable Angle LCP Forefoot/Midfoot System (K100776) and in adults and pediatric patients (2-12 years) when used with the DePuy Synthes Ti Wrist Fusion Plate (K023879).

The DePuy Synthes 3.5mm and 4.0mm Cortex Screws are intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur and fibula in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5mm Cortex Screw is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of non-unions or mal unions in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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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Device Name

DePuy Synthes Cortex Screws (4.0 mm and 4.5 mm), DePuy Synthes Cannulated Screws (2.4 mm, 3.5 mm, 4.0 mm, 4.5 mm, 6.5 mm, 7.0 mm, and 7.3 mm), DePuy Synthes Headless Compression Screws (1.5 mm and 2.4 mm), DePuy Synthes Headless Compression Screws (3.0 mm and 4.5 mm), DePuy Synthes Headless Compression Screws (6.5 mm) – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes 4.0 mm Cortex Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneus, femur, fibula and the bones of the foot and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm Cortex Screws are intended for fixation of fractures, fusion, osteotomies, non-unions, and malunions of various long bones, such as the humerus, femur and tibia; the pelvis of the foot and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 2.4 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones and small bone fragments in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments; and the bones of the hand and foot, in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 6.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. These screws are also indicated for femoral neck fractures; slipped capital femoral epiphysis; an adjunct to DHS in basilar neck fractures; tibial plateau fractures; ankle arthrodesis; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodesis.

The DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. These screws are also indicated for slipped capital femoral epiphysis; ankle arthrodesis; and subtalar arthrodesis.

The DePuy Synthes 1.5 mm Headless Compression Screws are intended for fixation of intra-articular and extra-articular fractures, avulsions, non-unions, malunions, and osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 2.4 mm Headless Compression Screws are intended for fixation of fractures, osteotomies, non-unions,

and malunions of small bones and small bone arthrodesis in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 3.0 mm Headless Compression Screws are intended for fixation of intra-articular and extra-articular fractures, non-unions, malunions, and osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screws are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of various bones and bone fragments including bones of the foot, humerus, femur and tibia in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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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)*
K192745

Device Name
DePuy Synthes 2.0 mm Quick Insertion Screws – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.0 mm Quick Insertion Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of the bones of the forefoot, midfoot, and hand in patients 2 years of age and older in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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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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)*
K192745

Device Name
DePuy Synthes Anatomical Locking Plate System (ALPS) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes ALPS is a plate and screw system intended to treat fractures of various long bones, including the radius, ulna, humerus, tibia, fibula, and femur.

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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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192745

Device Name
DePuy Synthes Sterile 3.0 mm Cannulated Screw and Threaded Washer – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.0 mm Cannulated Screw, used with the Threaded Washer, is generally intended for intra-articular fixation of small bones, such as the hand, wrist and forefoot. Specifically, it is intended for fractures of carpals and metacarpals, carpal and metacarpal arthrodesis; small fragments of the hand and wrist, and certain metatarsal - phalangeal applications (in foot). The 3.0 mm Cannulated Screw, by itself is intended for fixation of small bones, such as the hand, wrist and forefoot.

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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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192745

Device Name
DePuy Synthes Cannulated Angle Blade Plate (CAEP) System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes CABP System is a plate and screw system intended to treat fractures of the proximal humerus and distal tibia. Proximal humerus fractures include two-part greater tubercle fractures and fracture dislocations, two-part surgical neck fractures and fracture dislocations, three-part fractures or fracture dislocations, fractures in osteopenic bone, and nonunions and malunions. Distal tibia fractures include acute fractures, fractures in osteopenic bone, and nonunions 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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1. 510(k) Summary

Date Prepared: September 27, 2019

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Locking Condylar Plate (LCP) System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HTY, HWC, JDW

1.3. Predicate Device

K000066 Synthes Locking Condylar Plate (LCP) System

1.4. Device Description

The 4.0 mm locking screws feature a self-tapping tip, are solid, and have a flat head profile with rounded edges. They are available in lengths ranging from 14 mm to 62 mm. The threads just below the head of each locking screw engage with the threaded holes of the plate. The engagement of the screw to the plate shaft creates a locked fixed angle construct.

1.5. Indications for Use

The DePuy Synthes Locking Condylar Plate (LCP) System is intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar fractures, fractures in normal or osteopenic bone, and 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 Locking Condylar Plate (LCP) 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 Locking Condylar Plate (LCP) 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

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1.2. Device

Name of Device: DePuy Synthes Sacral Bar System – MR Conditional

Classification Name(s): Pin, Fixation, Threaded

Regulatory Class: Class II; 888.3040

Product Code(s): JDW

1.3. Predicate Device

K001720 Synthes Sacral Bar System

1.4. Device Description

The DePuy Synthes Sacral Bar System consists of a threaded bar, washers, and nuts. The bars are fully threaded. One end of the bar has a trocar point to guide the bar through pre-drilled holes. The bars are available in lengths ranging from 120 to 260 mm, in 10 min increments. The washers that are used with this system are oval shaped and are designed to slide freely along the bars. Both rounded and straight nuts are provided with this system; the rounded nuts mate with the washers to create compression, while the straight nuts are then added to wedge against the rounded nuts to maintain compression.

1.5. Indications for Use

The DePuy Synthes Sacral Bar System is intended for fixation of fractures of the posterior pelvis, in areas of the posterior superior iliac spine and posterior inferior iliac spine, for sacral fractures and fracture-dislocations of the sacro-iliac joint.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Sacral Bar 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 Sacral Bar 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).

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1.2. Device

Name of Device: DePuy Synthes Spiked Washer – MR Conditional

Classification Name(s): Washer, Bolt Nut

Regulatory Class: Class II; 888.3030

Product Code(s): HTN

1.3. Predicate Device

K011583 Synthes Spiked Washer

1.4. Device Description

The DePuy Synthes Spiked Washers are made of PEEK Optima™ LT plymer + 6% barium sulfate. There are either six or eight spikes arrayed around a center hole that will accommodate either 2.7, 3.5, 4.0, 4.5 or 6.6 mm screws.

1.5. Indications for Use

The DePuy Synthes Spiked Washer is intended for use in ligament reattachment or fixation, specifically re-adaptation of torn or avulsed ligaments.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Spiked Washer. 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 Spiked Washer 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

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1.2. Device

Name of Device: DePuy Synthes 4.0 mm Titanium (TI) Locking Screws – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K032559 Synthes 4.0 mm Titanium (TI) Locking Screws

1.4. Device Description

The DePuy Synthes 4.0 mm Titanium (TI) Locking Screws feature a self-tapping tip, stardrive mechanishm, and have a flat head profile with rounded edges. They are available in lengths ranging from 14 mm to 90 mm. The threads below the head of each locking screw are designed to engage with the threaded holes of currently marketed DePuy Synthes LCP plating systems.

1.5. Indications for Use

The DePuy Synthes 4.0 mm Titanium Locking Screws are intended to be used with existing DePuy Synthes LCP® plating systems for the fixation of various long bones, such as the humerus, femur and tibia.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 4.0 mm Titanium (TI) Locking Screws. 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 4.0 mm Titanium (TI) Locking Screws 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 27, 2019

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1.2. Device

Name of Device: DePuy Synthes 5.0/7.3 mm Cannulated Locking Screws – MR Conditional

Classification Name(s): Pin, Fixation, Threaded

Regulatory Class: Class II; 888.3040

Product Code(s): JDW

1.3. Predicate Device

K040765 Synthes 5.0/7.3 mm Cannulated Locking Screws

1.4. Device Description

The DePuy Synthes 5.0/7.3 mm Cannulated Locking Screws feature self-drilling and self-tapping tips, have a flat head profile with rounded edges with a hex drive recess. They are available in additional lengths ranging from 100 – 145 mm. The threads below the head of each locking screw are designed to engage with the threaded holes of currently marketed DePuy Synthes LCP® plating systems

1.5. Indications for Use

The DePuy Synthes 5.0/7.3 mm Cannulated Locking Screws are intended to be used with existing DePuy Synthes LCP® plating systems for the fixation of various long bones, such as the femur.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 5.0/7.3mm Cannulated Locking Screws. 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 5.0/7.3mm Cannulated Locking Screws 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

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1.2. Device

Name of Device: DePuy Synthes Peri-Prosthetic Screws – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC

1.3. Predicate Device

K041533 Synthes Peri-Prosthetic Screws

1.4. Device Description

The DePuy Synthes Peri-Prosthetic Screws feature a self-tapping blunt tip, stardrive mechanism, and have a flat head profile with rounded edges. They are available in lengths ranging from 8 mm to 12 mm. The threads on the head of each locking screw are designed to engage with the threaded holes of currently marketed DePuy Synthes LCP® plating systems.

1.5. Indications for Use

The DePuy Synthes Peri-Prosthetic Screws are intended for fixation of various long bones, such as the humerus, femur and tibia, in conjunction with DePuy Synthes Locking Plates that accept 4.0/5.0 mm locking screws. They are also for use in fixation of periprosthetic fractures, osteopenic bone, and fixation of nonunions or malunions.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Peri-Prosthetic Screws. 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 Peri-Prosthetic Screws 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

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1.2. Device

Name of Device: DePuy Synthes 3.5 mm Conical Screws – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC

1.3. Predicate Device

K050683 Synthes 3.5mm Conical Screws

1.4. Device Description

The DePuy Synthes 3.5 mm Conical Screws are self-tapping, have a stardrive or hex drive recess, and are manufactured from stainless steel and titanium. The 3.5 mm conical screws are available in various lengths ranging from 40-95 mm.

1.5. Indications for Use

The DePuy Synthes 3.5 mm Conical Screws are intended to be used with existing DePuy Synthes LCP plating systems for fixation and interfragmentary compression of various bones, such as the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia and fibula, particularly in osteopenic bone.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 3.5 mm Conical Screws. 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 3.5 mm Conical Screws 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

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1.2. Device

Name of Device: DePuy Synthes Spherical Washers – MR Conditional

Classification Name(s): Washer, Bolt, Nut, Non-Spinal, Metallic

Regulatory Class: Class II; 888.3030

Product Code(s): NDG, HWC

1.3. Predicate Device

K052483 Synthes Spherical Washers

1.4. Device Description

The DePuy Synthes Spherical Washers are round or oval in design with a slotted center hole which allows for screw angulation up to 70 degrees. They are used with 4.5 - 7.3 mm diameter screws and manufactured from Stainless Steel and Titanium.

1.5. Indications for Use

The DePuy Synthes Spherical Washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of large (long) bone and bone fragments.

In addition, the DePuy Synthes Spherical Washers are intended to prevent the projection of the screw head, when the screw must be inserted at an acute angle (e.g., in ankle arthrodesis).

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Spherical Washers. 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 Spherical Washers 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 27, 2019

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1.2. Device

Name of Device: DePuy Synthes 6.5 mm Cancellous Screws – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC

1.3. Predicate Device

K061621 Synthes 6.5 mm Cancellous Screws

1.4. Device Description

The DePuy Synthes 6.5 mm Cancellous Screws incorporate a fully threaded shaft, 4.0 mm core diameter, and have a flat head profile with rounded edges. They are available in lengths ranging from 60 mm to 130 mm in both Stainless Steel and Titanium Alloy. The screws are provided STERILE and NON STERILE.

1.5. Indications for Use

The DePuy Synthes 6.5 mm Cancellous Screws are intended for use in hindfoot and midfoot fusions, subtalar fusions, calcaneal osteotomies, midfoot reconstruction, and ankle arthrodeses.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 6.5 mm Cancellous Screws. 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 6.5 mm Cancellous Screws 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

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1.2. Device

Name of Device: DePuy Synthes 6.5 mm Midfoot Fusion Bolt – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC

1.3. Predicate Device

K081071 Synthes 6.5 mm Midfoot Fusion Bolt

1.4. Device Description

The DePuy Synthes 6.5 mm Midfoot Fusion Bolt is a solid metallic fixation bolt which is intended to be used in procedures involving the foot and ankle. The DePuy Synthes 6.5 mm Midfoot Fusion Bolt is partially threaded on both ends and will be available in versions composed of implant quality stainless steel and titanium alloy.

1.5. Indications for Use

The DePuy Synthes 6.5 mm Midfoot Fusion Bolt is indicated for fracture fixation, osteotomies, nonunions, and fusions of large bones in the foot and ankle.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 6.5 mm Midfoot Fusion Bolt. 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 6.5 mm Midfoot Fusion Bolt 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 27, 2019

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Cortical Screws – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC

1.3. Predicate Device

K112583 Synthes Cortical Screws

1.4. Device Description

The DePuy Synthes Cortical Screws have self-tapping features, stardrive, hexdrive, or cruciform head recesses, and are manufactured from stainless steel, commercially pure titanium, and/or titanium alloy. Cortex screws are offered both sterile and non sterile and are available in various lengths. Screws may be used independently or with any DePuy Synthes plate which accepts 1.0 mm, 1.3 mm, 2.0 mm, 2.4 mm, 2.7 mm, 3.5 mm, 4.0 mm, and 4.5 mm cortex screws. The screws, when used in pediatric applications, may be used independently or with compatible Synthes plates which are also indicated for pediatric populations.

1.5. Indications for Use

The DePuy Synthes 1.0mm, 1.3mm, 1.5mm, 2.0mm, and 2.4mm Cortex Screws are intended for use in trauma procedures, reconstructive procedures, and general surgery of the hand, wrist, and other small bones and bone fragments in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 2. 7mm Cortex Screw is intended for fractures and osteotomies of small bones and bone fragments, including the foot, ankle, and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. The DePuy Synthes 2. 7mm Cortex Screw may also be used in fusion applications in adults and adolescents (12-21 years) when used with the DePuy Synthes 2.4mm/2.7mm Variable Angle LCP Forefoot/Midfoot System (K100776) and in adults and pediatric patients (2-12 years) when used with the DePuy Synthes Ti Wrist Fusion Plate (K023879).

The DePuy Synthes 3.5mm and 4.0mm Cortex Screws are intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur and fibula in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5mm Cortex Screw is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of non-unions or mal unions in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Cortical Screws. 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 Cortical Screws 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 Cortex Screws (4.0 mm and 4.5 mm), DePuy Synthes Cannulated Screws (2.4 mm, 3.5 mm, 4.0 mm, 4.5 mm, 6.5 mm, 7.0 mm, and 7.3 mm), DePuy Synthes Headless Compression Screws (1.5 mm and 2.4 mm), DePuy Synthes Headless Compression Screws (3.0 mm and 4.5 mm), DePuy Synthes Headless Compression Screws (6.5 mm) – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC

1.3. Predicate Device

K161616 DePuy Synthes Cortex Screws (4.0 mm and 4.5 mm), DePuy Synthes Cannulated Screws (2.4 mm, 3.5 mm , 4.0 mm , 4.5 mm , 6.5 mm , 7.0 mm , and 7.3 mm), DePuy Synthes Headless Compression Screws (1.5 mm and 2.4 mm), DePuy Synthes Headless Compression Screws (3.0 mm And 4.5 mm), DePuy Synthes Headless Compression Screws (6.5 mm)

1.4. Device Description

The DePuy Synthes Cortex, Cannulated, and Headless Compression Screws are metallic bone screws manufactured from Stainless Steel (ASTM F138), Commercially Pure Titanium (ASTM F67), and/or Titanium Alloy (ASTM F1295). The screws are available in multiple lengths and diameters, and are intended to be used as stand-alone bone screws for internal bone fixation of fractures, fusions, osteotomies, non-unions, and malunions in adults and in both children (2-12

years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by the screw fixation.

The DePuy Synthes Cannulated and Headless Compression screws are cannulated for use with guidewires for precise placement in bone with the exception of the 1.5 mm Headless Compression Screw, which is a solid screw and therefore does not allow for instrumentation with a guide wire. The Headless Compression Screws feature threaded heads that allow for purchase in the near cortex of bone during and after implantation, potentially reducing complications associated with countersinking of traditional cortex or cannulated screws.

1.5. Indications for Use

The DePuy Synthes 4.0 mm Cortex Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneus, femur, fibula and the bones of the foot and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm Cortex Screws are intended for fixation of fractures, fusion, osteotomies, non-unions, and malunions of various long bones, such as the humerus, femur and tibia; the pelvis of the foot and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 2.4 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones and small bone fragments in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments; and the bones of the hand and foot, in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 6.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. These screws are also indicated for femoral neck fractures; slipped capital femoral

epiphysis; an adjunct to DHS in basilar neck fractures; tibial plateau fractures; ankle arthrodesis; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodesis.

The DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. These screws are also indicated for slipped capital femoral epiphysis; ankle arthrodesis; and subtalar arthrodesis.

The DePuy Synthes 1.5 mm Headless Compression Screws are intended for fixation of intra-articular and extra-articular fractures, avulsions, non-unions, malunions, and osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 2.4 mm Headless Compression Screws are intended for fixation of fractures, osteotomies, non-unions, and malunions of small bones and small bone arthrodesis in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 3.0 mm Headless Compression Screws are intended for fixation of intra-articular and extra-articular fractures, non-unions, malunions, and osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screws are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of various bones and bone fragments including bones of the foot, humerus, femur and tibia in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Cortex Screws (4.0 mm and 4.5 mm), DePuy Synthes Cannulated Screws (2.4 mm, 3.5 mm, 4.0 mm, 4.5 mm, 6.5 mm, 7.0 mm, and 7.3 mm), DePuy Synthes Headless Compression Screws (1.5 mm and 2.4 mm), DePuy Synthes Headless Compression Screws (3.0 mm and 4.5 mm), DePuy Synthes Headless Compression Screws (6.5 mm). 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 Cortex Screws (4.0 mm and 4.5 mm), DePuy Synthes Cannulated Screws (2.4 mm, 3.5 mm, 4.0 mm, 4.5 mm, 6.5 mm, 7.0 mm, and 7.3 mm), DePuy Synthes Headless Compression Screws (1.5 mm and 2.4 mm), DePuy Synthes Headless Compression Screws (3.0 mm and 4.5 mm), DePuy Synthes Headless Compression Screws (6.5 mm) 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 27, 2019

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes 2.0 mm Quick Insertion Screws – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC

1.3. Predicate Device

K180541 DePuy Synthes 2.0 mm Quick Insertion Screws

1.4. Device Description

The DePuy Synthes 2.0 mm Quick Insertion Screws (QI Screws) are twist-off style screws comprised of a screw and post which are intended to separate at a predefined location (the breakpoint) as the screw is implanted into bone. The screws are offered with an external thread diameter of 2.0 mm and in lengths ranging from 11 mm to 18 mm to accommodate varying patient anatomy and fracture patterns in the foot and hand. The screws are made of a titanium alloy (Ti-6Al-7Nb) in accordance with ASTM F1295.

1.5. Indications for Use

The DePuy Synthes 2.0 mm Quick Insertion Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of the bones of the forefoot, midfoot, and hand in patients 2 years of age and older in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.0 mm Quick Insertion Screws. 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 2.0 mm Quick Insertion Screws 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

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1.2. Device

Name of Device: DePuy Synthes Anatomical Locking Plate System (ALPS) – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC, HRS, JDS

1.3. Predicate Device

K961413 Synthes Anatomical Locking Plate System (ALPS)

1.4. Device Description

The DePuy Synthes ALPS is a plate and screw system intended to treat fractures of various long bones, including (but not limited to) the radius, ulna, humerus, tibia, fibula and femur. The ALPS utilizes a locking feature that secures the screw to the plate, enabling stable fixation to be achieved via unicortical or bicortical fixation. The locking feature consists of conical shaped, threaded screw holes in the plate that correspond wi th the conical-shaped, threaded head of the screw.

1.5. Indications for Use

The DePuy Synthes ALPS is a plate and screw system intended to treat fractures of various long bones, including the radius, ulna, humerus, tibia, fibula, and femur.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Anatomical Locking Plate System (ALPS). 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 Anatomical Locking Plate System (ALPS) 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

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1.2. Device

Name of Device: DePuy Synthes Sterile 3.0 mm Cannulated Screw and Threaded Washer – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC, HTN

1.3. Predicate Device

K962823 Synthes Sterile 3.0 mm Cannulated Screw and Threaded Washer

1.4. Device Description

The 3.0 mm Cannulated Screw has a 3.0 mm thread diameter and a 4.0 mm head diameter. It is available in short and long thread lengths ranging from 10 mm to 40 mm. It features self-drillinglself-tapping flutes and cancellous threads for use in cancellous bone. The screw is used in conjunction with a guide wire for precise placement in bone.

The Threaded Washer has a 5.5 mm thread diameter and is 3.0 mm in length. It features exterior threads for bone purcbase in the near cortex and is cylindrically shaped to allow passage of the 3.0 mm Cannulated Screw. The washer serves to provide a buttress in the near cortex for which the screw head can compress against.

1.5. Indications for Use

The DePuy Synthes Sterile 3.0 mm Cannulated Screw, used with the Threaded Washer, is generally intended for intra-articular fixation of small bones, such as the hand, wrist and forefoot. Specifically, it is intended for fractures of carpals and metacarpals, carpal and metacarpal arthrodesis; small fragments of the hand and wrist, and certain metatarsal - phalangeal applications (in foot). The 3.0 mm Cannulated Screw, by itself is intended for fixation of small bones, such as the hand, wrist and forefoot.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Sterile 3.0 mm Cannulated Screw and Threaded Washer. 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 Sterile 3.0 mm Cannulated Screw and Threaded Washer 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 Angle Blade Plate (CAEP) System – MR Conditional

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

Regulatory Class: Class II; 888.3030

Product Code(s): KTT

1.3. Predicate Device

K974537 Synthes Cannulated Angle Blade Plate (CAEP) System

1.4. Device Description

The DePuy Synthes Cannulated Angle Blade Plate is a straight plate with a blade at the head to allow for better fixation in the head of the humerus or in the distal tibia. The blade of the plate is cannulated to fit over a guide wire, allowing for the adjustment of the wire placement several times without adversely affecting the final result. There are cuts in the undersurface of the plate to reduce the surface area of the plate in contact with bone. The plate accepts 4.5 mm and 6.5 mm screws. he Cannulated Angle Blade Plate System is manufactured from stainless steel or commercially pure titanium.

1.5. Indications for Use

The DePuy Synthes CABP System is a plate and screw system intended to treat fractures of the proximal humerus and distal tibia. Proximal humerus fractures include two-part greater tubercle fractures and fracture dislocations, two-part surgical neck fractures and fracture dislocations, three-part fractures or fracture dislocations, fractures in osteopenic bone, and nonunions and malunions. Distal tibia fractures include acute fractures, fractures in osteopenic bone, and nonunions 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 Cannulated Angle Blade Plate (CAEP) 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 Cannulated Angle Blade Plate (CAEP) 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.