DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 30, 2017

Synthes (usa) Products LLC/depuy Orthopaedics Inc
Elizabeth Jacobs
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K160553

Trade/Device Name: DePuy Synthes 4.0 mm and 5.0 mm Locking Screws - MR Conditional, DePuy Synthes Wrist Fusion Plate (WFP) - MR Conditional, DePuy Synthes Large Fragment Dynamic Compression Locking (DCL) System -MR Conditional, DePuy Synthes Small Fragment Dynamic Compression Locking (DCL) System - MR Conditional, DePuy Synthes Modular Foot System - MR Conditional, DePuy Synthes T-Plates - MR Conditional, DePuy Synthes One-third Tubular Plate with Collar (OTPC) - MR Conditional, DePuy Synthes Stainless Steel Modular Hand System - MR Conditional, DePuy Synthes Ti-15 Mo Locking Distal Radius Plating System - MR Conditional, DePuy Synthes Hook Plate - MR Conditional, DePuy Synthes Cannulated Titanium Humeral Nail System - MR Conditional, DePuy Synthes Tibial Nail System Ex - MR Conditional, DePuy Synthes LCP® Curved Plates - MR Conditional, DePuy Synthes Elastic Intramedullary Nail (EIN) System - MR Conditional, DePuy Synthes LCP Wrist Fusion Plates - MR Conditional, DePuy Synthes Washer - MR Conditional, DePuy Synthes Modular Mini Fragment LCP System - MR Conditional, DePuy Synthes LCP Diaphyseal-Metaphyseal (Dia-Meta) Volar Distal Radius Plates - MR Conditional, DePuy Synthes Variable Angle-Locking Compression Plate (VA-LCP) Distal Radius System - MR Conditional, DePuy Synthes Stainless Steel Elastic Intramedullary Nail System - MR Conditional, DePuy Synthes Elastic Intramedullary Nail (EIN) End Cap - MR Conditional,DePuy Synthes Limited Contact - Dynamic Compression Plates (LC-DCP's) - MR Conditional, DePuy Synthes 2.4 mm VA-LCP Two Column Volar Distal Radius Plates - MR Conditional, DePuy Synthes 1.5 mm Mini Fragment LCP System - MR Conditional, DePuy Synthes 2.4 mm LCP Volar Column Distal Radius Plates - MR Conditional, DePuy Synthes Locking Hand Plates - MR Conditional, DePuy Synthes 2.4 mm VA-LCP Two-Column Narrow Volar Distal Radius - MR Conditional, DePuy Synthes 2.4 mm / 2.7 mm Variable Angle LCP Forefoot/Midfoot System - MR Conditional, DePuy Synthes 2.4 mm VA-LCP Dorsal Distal Radius Plates - MR Conditional, DePuy Synthes Multiloc Proximal Humeral Nailing System - MR Conditional, DePuy Synthes 2.4 mm VA-LCP

Intercarpal Fusion System - MR Conditional, DePuy Synthes 2.4 mm VA-LCP Volar Rim Distal Radius System - MR Conditional, DePuy Synthes 3.5mm Low Profile Cortical Screw - MR Conditional, DePuy Synthes LCP Pediatric Plate Systems - MR Conditional, DePuy Synthes Cortical Screws - MR Conditional, DePuy Synthes 2.7 mm LCP Ulna Osteotomy System - MR Conditional, DePuy Synthes 3.5 mm VA-LCP Proximal Tibia Plate System - MR Conditional, DePuy Synthes Multiloc Humeral Nailing System - MR Conditional, DePuy Synthes VA LCP Ankle Trauma System - MR Conditional, DePuy Synthes 2.7/3.5 mm Variable Angle LCP Ankle Trauma System - Anterolateral Distal Tibia Plate - MR Conditional, DePuy Synthes 2.7 mm and 3.5 mm Variable Angle LCP Midfoot/Hindfoot System - MR Conditional, 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), DePuySynthes Headless Compression Screws (1.5 mm and 2.4 mm), DePuy Synthes Headless Compression Screws (3.0 mm - MR Conditional, DePuy Synthes Condylar Buttress Plates - MR Conditional, DePuy Synthes Angled Blade Plate - MR Conditional, DePuy Synthes Unreamed Humeral Nail (URHN) - MR Conditional, DePuy Synthes Elastic Intramedullary Nail (EIN) System - MR Conditional, DePuy Synthes Distal Radius Plate System (DRPS) - MR Conditional, DePuy Synthes Calcaneal Plates - MR Conditional, DePuy Synthes Spiral Blade for Humeral Nail (SBHN) - MR Conditional, DePuy Synthes Kirschner (K-) Wires and Guide Wires - MR Conditional

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, HWC, JDS, KTT, KTW, LXT, HTY
Dated: June 1, 2017
Received: June 2, 2017

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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes 4.0 mm and 5.0 mm Locking Screws – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 4.0 mm and 5.0 mm Locking Screws are used for the static and dynamic interlocking of femoral, humeral and tibial nails.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes Wrist Fusion Plate (WFP) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Wrist Fusion Plates are intended for wrist arthrodesis and for fractures of other small long bones such as the clavicle and olecranon. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

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)*
K160553

Device Name
DePuy Synthes Large Fragment Dynamic Compression Locking (DCL) System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Large Fragment DCL is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions 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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K160553

Device Name
DePuy Synthes Small Fragment Dynamic Compression Locking (DCL) System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Small Fragment DCL system is indicated for the fixation of fractures, osteotomies. and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, 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)*
K160553

Device Name
DePuy Synthes Modular Foot System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Modular Foot System is intended for fractures, osteotomies, and replantations of small bones including the foot, ankle, and hand.

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)*
K160553

Device Name
DePuy Synthes T-Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Locking Compression Plate (LCP) System - T Plate are intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia. Also for use in fixation of osteopenic bone and fixation of 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)*
K160553

Device Name
DePuy Synthes One-third Tubular Plate with Collar (OTPC) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes One-Third Tubular Plate is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone as a part of the DePuy Synthes Small Fragment DCL 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)*
K160553

Device Name
DePuy Synthes Stainless Steel Modular Hand System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Stainless Steel Modular Hand System is intended for use in selective trauma, reconstructive procedures, and general surgery of the hand, wrist, and other small bones.

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)*
K160553

Device Name
DePuy Synthes Ti-15 Mo Locking Distal Radius Plating System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Ti-15 Mo Locking Distal Radius Plating System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

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 Hook Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Proximal Femur Hook Plates are intended for fractures of the femur including: fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, intertrochanteric reversed, or transverse or with additional fracture of medial cortex. Fractures of the proximal end of the femur combined with ispsilateral shaft fractures, metastatic fracture of the proximal femur and osteotomies of the proximal 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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510(k) Number *(if known)*
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Device Name
DePuy Synthes Cannulated Titanium Humeral Nail System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Titanium Cannulated Humeral Nail System is intended to aid in the alignment and stabilization of humeral fractures to include: Diaphyseal fractures of the humeral shaft, Fractures of the proximal humerus, Proximal humeral fractures with diaphyseal extension, Impending pathologic fractures, and 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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Device Name
DePuy Synthes Tibial Nail System Ex – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Tibial Nail System Ex is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post -isthmic fractures; and tibial malunions and 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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Device Name
DePuy Synthes LCP® Curved Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Curved Broad Plates are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of peri-prosthetic fractures, osteopenic bone and non-unions or malunions.

The DePuy Synthes Curved Condylar Plates are intended for buttressing multifragmentary distal femur fractures, including: supracondylar, intra-articular and extra-articular condylar fractures, peri-prosthetic fractures and fractures in normal or osteopenic bone, nonunions/malunions, and osteotomies of the femur.

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

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

Indications for Use *(Describe)*
The DePuy Synthes Elastic Intramedullary Nail (EIN) System 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)*

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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes LCP Wrist Fusion Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Wrist Fusion Plates are intended for wrist arthrodesis and fractures of other small bones. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

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)*
K160553

Device Name
DePuy Synthes Washer – 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)*
K160553

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

Indications for Use *(Describe)*
The DePuy Synthes Elastic Intramedullary Nail (EIN) System 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)*
K160553

Device Name
DePuy Synthes Modular Mini Fragment LCP System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Modular Mini Fragment LCP System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, 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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510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes LCP Diaphyseal-Metaphyseal (Dia-Meta) Volar Distal Radius Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Dia-Meta Volar Distal Radius Plates are indicated for fractures, osteotomies, and non-unions of the radius and other small bones.

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)*
K160553

Device Name
DePuy Synthes Variable Angle-Locking Compression Plate (VA-LCP) Distal Radius System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes VA-LCP Distal Radius System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

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)*
K160553

Device Name
DePuy Synthes Stainless Steel Elastic Intramedullary Nail System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Elastic Intramedullary Nail (EIN) System 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)*
K160553

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

Indications for Use *(Describe)*
The DePuy Synthes Elastic Intramedullary Nail (EIN) System 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)*
K160553

Device Name
DePuy Synthes Limited Contact - Dynamic Compression Plates (LC-DCP's) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm Locking Compression Plate CLCP) System: The Synthes 3.5 mm LCP is indicated for fixation offractures, osteotomies and non-unions ofthe clavicle, scapula, olectranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone for adult patients.

These plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones in pediatric patients.

The DePuy Synthes 4.5 mm Locking Compression Plate CLCP) System: The Synthes 4.5 LCP is indicated for fixation ofvarious long bones, such as the humerus, femur and tibia and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients.

These plates are also indicated for fracture flXation of diaphyseal and metaphyseal areas of long bones in pediatric 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)*
K160553

Device Name
DePuy Synthes 2.4 mm VA-LCP Two Column Volar Distal Radius Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.4 mm VA-LCP Two-Column Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

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)*
K160553

Device Name
DePuy Synthes 1.5 mm Mini Fragment LCP System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 1.5 mm Mini Fragment LCP System is indicated for fixation of small bones and small fragments, osteotomies, arthrodeses, replantations, and reconstructions of small bones and small fragments, 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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Indications for Use

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510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes 2.4 mm LCP Volar Column Distal Radius Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.4 mm LCP Volar Column Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures of and osteotomies of the distal radius and other small bones.

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)*
K160553

Device Name
DePuy Synthes Locking Hand Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Locking Hand Plates are intended for fixation of fractures, osteotomies, non-unions, replantations and fusions of small bones and small bone fragments, 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)*
K160553

Device Name
DePuy Synthes 2.4 mm VA-LCP Two-Column Narrow Volar Distal Radius – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.4 mm VA-LCP Two-Column Narrow Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

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)*
K160553

Device Name
DePuy Synthes 2.4 mm / 2.7 mm Variable Angle LCP Forefoot/Midfoot System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.4 mm / 2.7 mm VA-LCP Forefoot / Midfoot System is indicated for fixation of osteotomies, fusions, fractures, non unions, mal unions and replantations of small bones and small bone fragments in adult and adolescent (12- 21 years) patients, including the foot and ankle, and 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)*
K160553

Device Name
DePuy Synthes 2.4 mm VA-LCP Dorsal Distal Radius Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.4 mm LCP Distal Radius System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra:articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.
The 2.4 mm LCP Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

The DePuy Synthes 2.4 mm Variable Angle LCP Two-Column Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

The DePuy Synthes 2.4mm Variable Angle LCP Two-Column Narrow Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

continued

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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The DePuy Synthes Variable Angle LCP Distal Radius System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

The DePuy Synthes Synthes Locking Distal Radius Plating System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

The DePuy Synthes Ti-15Mo Locking Distal Radius Plating System Distal System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

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Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes Multiloc Proximal Humeral Nailing System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes MultiLoc Proximal Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part 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)*
K160553

Device Name
DePuy Synthes 2.4 mm VA-LCP Intercarpal Fusion System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.4 mm V A-LCP Intercarpal Fusion System is indicated for fusion of small bones of the hand including: hamate, capitate, lunate, and triquetrum, for the revision of failed partial wrist fusions, and is indicated for use in patients suffering pain and/or loss of function due to: Osteoarthritis, Rheumatoid arthritis, Post-traumatic or degenerative wrist arthritis, Carpal instability.

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: January 31, 2017
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510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes 2.4 mm VA-LCP Volar Rim Distal Radius System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.4 mm Variable Angle LCP Volar Rim Distal Radius Plates are indicated for fixation of complex intra- and extra-articular fractures of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intraarticular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

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)*
K160553

Device Name
DePuy Synthes 3.5mm Low Profile Cortical Screw – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm Low Profile Cortical Screws are intended for fixation of ITactures, 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 the 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
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Indications for Use

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510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes LCP Pediatric Plate Systems – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Pediatric LCP Plate System is indicated for fixation of fractures (including pathologic and impending pathologic fractures) and osteotomies of the femur in infants, children, adolescents and small statured adults.

Specific indications for the 100°, 120°, 130°, 140°, 150° plates include:
• Varus, valgus, rotational and/or shortening osteotomies
• Femoral neck and/or pertrochanteric fractures
• Proximal metaphyseal fractures
• Diaphyseal fractures
• Pathologic fractures
• Prophylactic use for impending pathologic fractures

Specific indications for the 90° plates include:
• Varus, valgus, rotational and/or shortening osteotomies
• Femoral neck and/or penrochanteric fractures
• Proximal and distal metaphyseal fractures
• Diaphyseal fractures
• Pathologic fractures
• Prophylactic usc for impending pathologic 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)*
K160553

Device Name
DePuy Synthes Cortical Screws – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 1.0 mm, 1.3 mm, 1.5 mm, 2.0 mm, and 2.4 mm 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 2.7 mm 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 Synthes 2.7 mm Cortex Screw may also be used in fusion applications in adults and adolescents (12-21 years) when used with the Synthes 2.4 mm / 2.7 mm Variable Angle LCP Forefoot/Midfoot System (K100776) and in adults and pediatric patients (2-12 years) when used with the Synthes Ti Wrist Fusion Plate (K023879).

The DePuy Synthes 3.5 mm and 4.0 mm 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 4.5 mm 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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510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes 2.7 mm LCP Ulna Osteotomy System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.7 mm LCP Ulna Osteotomy System is indicated for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, including osteopenic bone in the ulna. The 2.7 mm LCP Ulna Osteotomy System is indicated for use in both adults 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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510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes 3.5 mm VA-LCP Proximal Tibia Plate System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm VA-LCP Proximal Tibia Plates are intended to treat fractures of the proximal tibia in adults and adolescents in which the growth plates have fused including: simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures. Plates can also be used for treatment of nonunions, mal unions, tibial osteotomies and 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)*
K160553

Device Name
DePuy Synthes Multiloc Humeral Nailing System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes MultiLoc Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal humeral fractures with diaphyseal extension, diaphyseal fractures of the humeral shaft, and impending pathologic humeral 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)*
K160553

Device Name
DePuy Synthes VA LCP Ankle Trauma System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Variable Angle LCP Ankle Trauma System is intended for fixation of the ankle in adults and adolescents (12-21) in which the growth plates have fused, and particularly in osteopenic bone. Specifically,
• Medial and Anteromedial Distal Tibia Plates are intended for fixation of osteotomies, fractures, non unions, mal unions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,
• Distal Tibia T Plates and Distal Tibia L Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia, and
• Lateral Distal Fibula Plates are intended for fixation of osteotomies, fractures, non unions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.

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)*
K160553

Device Name
DePuy Synthes 2.7/3.5 mm Variable Angle LCP Ankle Trauma System-Anterolateral Distal Tibia Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.7/3.5 mm Variable Angle LCP Ankle Trauma System is intended Indications for Use for fixation of the ankle and is indicated in adults and adolescents (12-21) in which the growth plates have fused, and particularly in osteopenic bone.
Specifically,
• Anterolateral Distal Tibia Plates are intended for fixation of osteotomies, fractures, non unions, mal unions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia.
• Medial and Anteromedial Distal Tibia Plates are intended for fixation of osteotomies, fractures, non unions, mal unions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,
• Distal Tibia T Plates and Distal Tibia L Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia, and
• Lateral Distal Fibula Plates are intended for fixation of osteotomies, fractures, nonunions, mal unions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.

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)*
K160553

Device Name
DePuy Synthes 2.7 mm and 3.5 mm Variable Angle LCP Midfoot/Hindfoot System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.7 mm and 3.5 mm Variable Angle LCP Midfoot/Hindfoot System is indicated for fixation of osteotomie, fusions, fractures, nonunions, malunions and replantations of small bones and small one fragments in adult and adolescent (12 -21 years) patients, including the foot and ankle, and particularly in osteopenic bone.

The DePuy Synthes 3.5 mm Low Profile Cortical Screws and the Synthes 3.5 mm Cortex Screws are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, hand, radius, ulna, pelvis, tibia, femur, fibula, 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 the 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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510(k) Number *(if known)*
K160553

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 – 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; 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 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.

continued

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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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.

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Food and Drug Administration

Indications for Use

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510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes Condylar Buttress Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Variable Angle Positioning Pins are intended for use with cerclage multifilament cable to augment fracture stabilization with plates used in long bone fixation, when screw placement would be inhibited, as in the presence of intramedullary implant. The Variable Angle Positioning Pins are designed for use with Variable Angle LCP plate implants featuring variable angle locking holes that accept 5.0 mm variable angle bone screws.

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)*
K160553

Device Name
DePuy Synthes Angled Blade Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Angled Blade Plate is intended for use in femoral fractures and osteotomies. More specifically, the primary intended uses are as follows:

- fractures of the distal and proximal femur
- femoral neck and pertrochanteric fractures
- intertrochanteric femoral osteotomies
- repositioning osteotomy (femoral neck)

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)*
K160553

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

Indications for Use *(Describe)*
The DePuy Synthes Unreamed Humeral Nail (URHN) is generally indicated for Humeral shaft fractures. Specifically,
• Acute humeral shaft fractures;
• Pathologic or impending pathologic fractures;
• Non and malunions 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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Food and Drug Administration
Office of Chief Information Officer
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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160553

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

Indications for Use *(Describe)*
The DePuy Synthes EIN 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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See PRA Statement below.

510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes Distal Radius Plate System (DRPS) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Distal Radius Plate System is intended for fixation of fractures, osteotomies, including carpal fusions involving the distal radius applied to the volar and dorsal aspect.

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)*
K160553

Device Name
DePuy Synthes Calcaneal Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Locking Calcaneal Plates are indicated for fractures and osteotomies of the calcaneus, including, but not limited to extra-articular, intra-articular, joint depression, tongue type and severely comminuted 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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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160553

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

Indications for Use *(Describe)*
The DePuy Synthes Spiral Blade for Humeral Nail 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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Indications for Use

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510(k) Number *(if known)*
K160553

Device Name
DePuy Synthes Kirschner (K-) Wires and Guide Wires – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Kirschner (K-) Wires and Guide Wires are indicated for use in open and percutaneous fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants, for implantation through the skin, and as traction pins so that traction may be applied to the skeletal 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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1. 510(k) Summary

Date Prepared: June 01, 2017

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes 4.0 mm and 5.0 mm Locking Screws – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC

1.3. Predicate Device

K000089 DePuy Synthes 4.0 mm and 5.0 mm Locking Screws

1.4. Device Description

The DePuy Synthes 4.0 mm and 5.0 mm Locking Screws are an added option to the 3.9 mm and 4.9 mm Locking Bolts. The locking screws are used in conjunction with Synthes intramedullary nails to stabilize fractures of the tibia, humerus and femur. The Locking Screws are designed with a Synthes truncated cortex screw thread profile and a double lead thread to allow a progression through bone similar to the locking bolt. The tip of the 4.0 mm and 5.0 mm Locking Screws is trocar, selftapping and the core diameters are 3.3 mm and 4.3 mm, respectively. The locking screws are available in lengths ranging from 18 - 80 mm (4.0 mm) and 26 - 100 mm (5.0 mm).

1.5. Indications for Use

The DePuy Synthes 4.0 mm and 5.0 mm Locking Screws are used for the static and dynamic interlocking of femoral, humeral and tibial nails.

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 and 5.0 mm 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 and 5.0 mm 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.

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1.2. Device

Name of Device: DePuy Synthes Wrist Fusion Plate (WFP) – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, LXT

1.3. Predicate Device

K000558 DePuy Synthes Wrist Fusion Plate (WFP)

1.4. Device Description

The DePuy Synthes Wrist Fusion Plate (WFP) feature a limited-contact profile and dynamic compression unit (DCU) screw holes which accept 3.5 mm cortex and 2.7 mm cortex screws. The plates are available in three designs (standard, short, and straight) to accommodate the anatomic needs of the patient. The standard plate accommodates average-sized individuals; the short bend plate fits small-statured individuals or patients with previous proximal row carpectomy; and the straight plate may be contoured to unusual anatomy or the severely deformed wrist joint. The straight plate also accommodates patients with severe bone loss requiring a corticocancellous strut from the iliac crest. The standard plate and short bend plates have a built-in fusion angle of 10° dorsiflexion, and are 112 mm in length. These plates feature a pre-contoured carpal bend. The straight plate is 110 mm in length without the carpal bend and built-in fusion angle.

1.5. Indications for Use

The DePuy Synthes Wrist Fusion Plates are intended for wrist arthrodesis and for fractures of other small long bones such as the clavicle and olecranon. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Wrist Fusion Plate (WFP). 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 Wrist Fusion Plate (WFP) 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 Large Fragment Dynamic Compression Locking (DCL) System – MR Conditional

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

Regulatory Class: Class II; 888.3030

Product Code(s): KTT, HRS

1.3. Predicate Device

K000682 DePuy Synthes Large Fragment Dynamic Compression Locking (DCL) System

1.4. Device Description

The DePuy Synthes Large Fragment DCL system consists of limited-contact profile plates in broad and narrow sizes, which include combination dynamic compression/locking screw holes. The plates accept 4.5 mm cortex, 6.5 mm cancellous, 4.5 mm cannulated, 7.0 mm cannulated, and 5.0 mm locking screws. This device is manufactured in either stainless steel or titanium.

1.5. Indications for Use

The DePuy Synthes Large Fragment DCL is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions 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 Large Fragment Dynamic Compression Locking (DCL) 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 Large Fragment Dynamic Compression Locking (DCL) 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 Small Fragment Dynamic Compression Locking (DCL) System – MR Conditional

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

Regulatory Class: Class II; 888.3030

Product Code(s): KTT, HRS

1.3. Predicate Device

K000684 DePuy Synthes Small Fragment Dynamic Compression Locking (DCL) System

1.4. Device Description

The DePuy Synthes Small Fragment DCL system consists of limited-contact profile plates in straight, reconstruction, Oblique T- and Small T- plates of various sizes and 3.5 mm locking screws. The plates in this system also accept 2.7 mm and 3.5 mm cortex, and 4.0 mm cancellous screws. The plates feature a combination dynamic compression/locking screw hole. The system is available in either stainless steel or titanium.

1.5. Indications for Use

The DePuy Synthes Small Fragment DCL system is indicated for the fixation of fractures, osteotomies. and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, 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 Small Fragment Dynamic Compression Locking (DCL) 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 Small Fragment Dynamic Compression Locking (DCL) 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 Modular Foot System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K001941 DePuy Synthes Modular Foot System

1.4. Device Description

The DePuy Synthes Modular Foot System is a series of plates and screws with plates of varying lengths and thicknesses and configurations including T-, LC-DCP, Condylar, and Cuboid Plates. These plates are attached to bone via 1.8 mm buttress pins and 2.0 mm and 2.4 mm self-tapping cortex screws.

1.5. Indications for Use

The DePuy Synthes Modular Foot System is intended for fractures, osteotomies, and replantations of small bones including the foot, ankle, and hand.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Modular Foot 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 Modular Foot 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 T-Plates – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K010766 DePuy Synthes T-Plates

1.4. Device Description

The DePuy Synthes Locking Compression Plate (LCP) System - T Plate is a buttress plate and screw system. The primary feature of the plate is round holes combined with locking screw holes. The locking screws form a locked, fixed angle construct with the plate, while the standard screws facilitate reduction and create compression between the plate and bone.

The plates accept 4.5 mm cortex, 6.5 mm cancellous, 4.5 mm cannulated, 7.0 mm cannulated, 7.3 mm cannulated, 4.0 mm and 5.0 mm locking screws.

1.5. Indications for Use

The DePuy Synthes Locking Compression Plate (LCP) System - T Plate are intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia. Also for use in fixation of osteopenic bone and fixation of 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 T-Plates. 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 T-Plates 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 One-third Tubular Plate with Collar (OTPC) – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K011335 DePuy Synthes One-third Tubular Plate with Collar (OTPC)

1.4. Device Description

The DePuy Synthes One-Third Tubular DCL Plate line extension is a threaded version of the currently marketed Synthes Third Tubular Plate. The threaded plates will accept locking screws and therefore can be included as part of the The DePuy Synthes Small Fragment DCL System. The plates have the same intended use as other plates in the system and there is no change in safety or efficacy.

1.5. Indications for Use

The DePuy Synthes One-Third Tubular Plate is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone as a part of the DePuy Synthes Small Fragment DCL System.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes One-third Tubular Plate with Collar (OTPC). 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 One-third Tubular Plate with Collar (OTPC) 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: June 01, 2017

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1.2. Device

Name of Device: DePuy Synthes Stainless Steel Modular Hand System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K030310 DePuy Synthes Stainless Steel Modular Hand System

1.4. Device Description

The DePuy Synthes Stainless Steel Modular Hand System is a series of plates and screws of varying lengths and thic1mess, and configurations including straight, T-, Y-, and extended H-plates. These plates are attached to bone via 1.8 mm buttress pins and 1.0 mm, 1.3 mm, 1.5 mm, 2.0 mm, and 2.4 mm self-tapping cortex screws.

1.5. Indications for Use

The DePuy Synthes Stainless Steel Modular Hand System is intended for use in selective trauma, reconstructive procedures, and general surgery of the hand, wrist, and other small bones.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Stainless Steel Modular Hand 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 Stainless Steel Modular Hand 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 Ti-15 Mo Locking Distal Radius Plating 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

K031725 DePuy Synthes Ti-15 Mo Locking Distal Radius Plating System

1.4. Device Description

The DePuy Synthes Ti-15Mo Locking Distal Radius Plating System consists of machined metallic plates and screws that offer screw to plate locking designed for various fracture modes of the distal end of the radius.

1.5. Indications for Use

The DePuy Synthes Ti-15 Mo Locking Distal Radius Plating System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Ti-15 Mo Locking Distal Radius Plating 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 Ti-15 Mo Locking Distal Radius Plating 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: June 01, 2017

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Hook Plate – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K032032 DePuy Synthes Hook Plate

1.4. Device Description

The DePuy SynthesLCP Proximal Femur Hook Plates are contoured to match the anatomy of the proximal femur with a limited contact low profile design. The plate has dynamic compression holes combined with conical shaped threaded screw holes, which accept 4.5 mm cortex, 4.5 mm shaft screws, 4.0 mm or 5.0 mm locking screws, 5.0 mm cannulated screws, and 7.3 mm cannulated locking & cannulated conical screws. The plates are available in a various lengths

1.5. Indications for Use

The DePuy Synthes LCP Proximal Femur Hook Plates are intended for fractures of the femur including: fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, intertrochanteric reversed, or transverse or with additional fracture of medial cortex. Fractures of the proximal end of the femur combined with ispsilateral shaft fractures, metastatic fracture of the proximal femur and osteotomies of the proximal femur.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Hook Plate. 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 Hook Plate 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 Titanium Humeral Nail System – MR Conditional

Classification Name(s): Nail, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): JDS

1.3. Predicate Device

K033071 DePuy Synthes Cannulated Titanium Humeral Nail System

1.4. Device Description

The DePuy Synthes Titanium Cannulated Humeral Nail System consists of cannulated titanium intramedullary rods, and end caps in a variety of sizes designed for treatment of various humeral fractures. A 2.0 mm guide wire is used with the system.

1.5. Indications for Use

The DePuy Synthes Titanium Cannulated Humeral Nail System is intended to aid in the alignment and stabilization of humeral fractures to include: Diaphyseal fractures of the humeral shaft, Fractures of the proximal humerus, Proximal humeral fractures with diaphyseal extension, Impending pathologic fractures, and 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 Cannulated Titanium Humeral 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 Cannulated Titanium Humeral 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 Tibial Nail System Ex – MR Conditional

Classification Name(s): Nail, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): JDS

1.3. Predicate Device

K040762 DePuy Synthes Tibial Nail System Ex

1.4. Device Description

The DePuy Synthes Tibial Nail System Ex is composed of cannulated tibial nails, 5.0 mm dual core locking screws and end caps. The 5.0 mm dual core locking screws, end caps, and Synthes commercially available 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 Tibial Nail System Ex is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post - isthmic fractures; and tibial malunions and 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 Tibial Nail System Ex. 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 Tibial Nail System Ex 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® Curved Plates – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K041911 DePuy Synthes LCP® Curved Plates

1.4. Device Description

The DePuy Synthes LCP® Curved Plates have a slight curve to better match the anatomy of the bone. The plates have a limited contact profile design and includes combination dynamic compression/locking screw holes.

1.5. Indications for Use

The DePuy Synthes Curved Broad Plates are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of peri-prosthetic fractures, osteopenic bone and non-unions or malunions.

The DePuy Synthes Curved Condylar Plates are intended for buttressing multifragmentary distal femur fractures, including: supracondylar, intra-articular and extra-articular condylar fractures, peri-prosthetic fractures and fractures in normal or osteopenic bone, nonunions/malunions, and osteotomies of 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 Spoon Plates. 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 Spoon Plates 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 – MR Conditional

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

Regulatory Class: Class II; 888.3020

Product Code(s): HSB

1.3. Predicate Device

K042135 DePuy Synthes Elastic Intramedullary Nail (EIN) System

1.4. Device Description

The DePuy Synthes EIN system 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 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. 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.

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1.2. Device

Name of Device: DePuy Synthes LCP Wrist Fusion Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K042355 DePuy Synthes LCP Wrist Fusion Plates

1.4. Device Description

The DePuy Synthes LCP Wrist Fusion Plates are pre-contoured with a limited contact design utilizing a short bend with a 3.3 mm thickness and a width of 11 mm. The plate uses a total of 10 combination holes which utilizes 2.7 mm and 3.5 mm cortex and locking screws. The plates are available in Titanium and Stainless Steel.

1.5. Indications for Use

The DePuy Synthes LCP Wrist Fusion Plates are intended for wrist arthrodesis and fractures of other small bones. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes LCP Wrist Fusion Plates. 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 Wrist Fusion Plates 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 Washer – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II; 888.3030

Product Code(s): HTN

1.3. Predicate Device

K052483 DePuy Synthes Washer

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 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 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 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 Elastic Intramedullary Nail (EIN) End Cap – MR Conditional

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

Regulatory Class: Class II; 888.3020

Product Code(s): HSB

1.3. Predicate Device

K053105 DePuy Synthes Elastic Intramedullary Nail (EIN) End Cap

1.4. Device Description

The DePuy Synthes Elastic Intramedullary Nail (EIN) End Cap is used with the Synthes Elastic Intramedullary Nail (EIN) System. The Titanium Elastic Nail End Cap is inserted over the external portion of the nail and threaded into the cancellous bone in an oblique orientation. The threads are self-tapping with reverse cutting flutes to facilitate end cap removal. The back end of the cap is blunt to minimize soft tissue irritation.

1.5. Indications for Use

The DePuy Synthes Elastic Intramedullary Nail (EIN) System 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) End Cap. 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) End Cap 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 Modular Mini Fragment LCP System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K063049 DePuy Synthes Modular Mini Fragment LCP System

1.4. Device Description

The DePuy Synthes Modular Mini Fragment LCP System includes 2.0 mm, 2.4 mm, and 2.7 mm size implants. The system incorporates a series of locking compression plates and screws of varying lengths, thicknesses, and configurations including straight, condylar, T-, Y-, adaption plates. These plates are attached to bone via 2.0 mm, 2.4 mm, and 2.7 mm cortex and locking screws.

1.5. Indications for Use

The DePuy Synthes Modular Mini Fragment LCP System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, 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 Modular Mini Fragment 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 Modular Mini Fragment 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.

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1.2. Device

Name of Device: DePuy Synthes LCP Diaphyseal-Metaphyseal (Dia-Meta) Volar Distal Radius Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K070946 DePuy Synthes LCP Diaphyseal-Metaphyseal (Dia-Meta) Volar Distal Radius Plates

1.4. Device Description

The DePuy Synthes LCP Dia-Meta Volar Distal Radius Plates provide stable fixation for radius fractures. The plates have threaded locking holes in the head of the plate that accept 2.4 mm locking screws, and dynamic compression holes combined with locking holes in the shaft of the plate which accept 3.5 mm cortex, 3.5 mm locking, or 4.0 mm cancellous screws. The plates are available in various lengths and are available in right and left versions to accommodate varying patient anatomy. The plates are manufactured in either titanium or stainless steel.

1.5. Indications for Use

The DePuy Synthes LCP Dia-Meta Volar Distal Radius Plates are indicated for fractures, osteotomies, and non-unions of the radius and other small bones.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes LCP Diaphyseal-Metaphyseal (Dia-Meta) Volar Distal Radius Plates. 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 Diaphyseal-Metaphyseal (Dia-Meta) Volar Distal Radius Plates 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 Variable Angle-Locking Compression Plate (VA-LCP) Distal Radius System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K071184 DePuy Synthes Variable Angle-Locking Compression Plate (VA-LCP) Distal Radius System

1.4. Device Description

The DePuy Synthes VA-LCP Distal Radius System consists of machined metallic plates and screws that offer screw to plate locking designed for various fracture modes of the distal portion of the radius.

The DePuy Synthes VA-LCP Distal Radius System enhances fragment-specific fracture fixation by providing the flexibility to lock screws in trajectories that can diverge from the central axis of the plate hole.

1.5. Indications for Use

The DePuy Synthes VA-LCP Distal Radius System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Variable Angle-Locking Compression Plate (VA-LCP) Distal Radius 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 Variable Angle-Locking Compression Plate (VA-LCP) Distal Radius 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 Stainless Steel Elastic Intramedullary Nail System – MR Conditional

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

Regulatory Class: Class II; 888.3020

Product Code(s): HSB

1.3. Predicate Device

K081452 DePuy Synthes Stainless Steel Elastic Intramedullary Nail System

1.4. Device Description

The DePuy Synthes Stainless Steel Elastic Intramedullary Nail System consists of intramedullary fixation devices that vary in diameters and lengths, which can be cut to size intra-operatively. The nails have a curved tip to facilitate insertion and manipUlation. The end cap is inserted over the external portion ofthe nail and threaded into the cancellous bone.

1.5. Indications for Use

The DePuy Synthes Elastic Intramedullary Nail (EIN) System 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 Stainless Steel Elastic Intramedullary 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 Stainless Steel Elastic Intramedullary 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) End Cap – MR Conditional

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

Regulatory Class: Class II; 888.3020

Product Code(s): HSB

1.3. Predicate Device

K082148 DePuy Synthes Elastic Intramedullary Nail (EIN) End Cap

1.4. Device Description

The DePuy Synthes Elastic Intramedullary Nail (EIN) End Cap is used with the Synthes Elastic Intramedullary Nail (EIN) System. The end cap is inserted over the external portion of the nail and threaded into the cancellous bone in an oblique orientation.

1.5. Indications for Use

The DePuy Synthes Elastic Intramedullary Nail (EIN) System 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) End Cap. 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) End Cap 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: June 01, 2017

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1.2. Device

Name of Device: DePuy Synthes Limited Contact - Dynamic Compression Plates (LC-DCP's) – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K082807 DePuy Synthes Limited Contact - Dynamic Compression Plates (LC-DCP's)

1.4. Device Description

The DePuy Synthes 3.5 mm and 4.5 mm LCP Plates with Expanded Indications consist of 3.5 mm LCP plates, 4.5 mm Narrow LCP Plates, 4.5 mm Broad LCP plates and 4.5 mm Curved Broad LCP Plates for fracture fixation in adults and pediatric patients. These plates accept locking, cortex and cancellous screws.

1.5. Indications for Use

The DePuy Synthes 3.5 mm Locking Compression Plate CLCP) System: The Synthes 3.5 mm LCP is indicated for fixation offractures, osteotomies and non-unions ofthe clavicle, scapula, olectranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone for adult patients.

These plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones in pediatric patients.

The DePuy Synthes 4.5 mm Locking Compression Plate CLCP) System: The Synthes 4.5 LCP is indicated for fixation ofvarious long bones, such as the humerus, femur and tibia and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients.

These plates are also indicated for fracture flXation of diaphyseal and metaphyseal areas of long bones in pediatric patients.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Limited Contact - Dynamic Compression Plates (LC-DCP's). 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 Limited Contact - Dynamic Compression Plates (LC-DCP's) 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 2.4 mm VA-LCP Two Column Volar Distal Radius Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K083694 DePuy Synthes 2.4 mm VA-LCP Two Column Volar Distal Radius Plates

1.4. Device Description

The DePuy Synthes 2.4 mm Variable Angle LCP (VA-LCP) Two-Column Volar Distal Radius Plate is a machined metal plate that is designed for fixation of various fracture modes of the distal portion of the radius. The 2.4 mm VA-LCP Two-Column Volar Distal Radius plate allows fragment-specific fracture fixation by providing the flexibility to lock screws in the head or shaft of the plate in trajectories that can diverge from the central axis of the plate hole. The DePuy Synthes' variable angle locking technology enhances plate-screw construct stability. The plates are manufactured in either titanium or stainless steel.

1.5. Indications for Use

The DePuy Synthes 2.4 mm VA-LCP Two-Column Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.4 mm VA-LCP Two Column Volar Distal Radius Plates. 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 2.4 mm VA-LCP Two Column Volar Distal Radius Plates 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 1.5 mm Mini Fragment LCP System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K090047 DePuy Synthes 1.5 mm Mini Fragment LCP System

1.4. Device Description

The DePuy Synthes 1.5 mm Mini Fragment LCP System consists of lowprofile plates of various shapes as well as locking and cortex screws which are intended to treat small bones and small fragments. The plates and screws of the 1.5 mm Mini Fragment LCP System are available in stainless steel and titanium.

1.5. Indications for Use

The DePuy Synthes 1.5 mm Mini Fragment LCP System is indicated for fixation of small bones and small fragments, osteotomies, arthrodeses, replantations, and reconstructions of small bones and small fragments, 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 1.5 mm Mini Fragment 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 1.5 mm Mini Fragment 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.

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1.2. Device

Name of Device: DePuy Synthes 2.4 mm LCP Volar Column Distal Radius Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K091644 DePuy Synthes 2.4 mm LCP Volar Column Distal Radius Plates

1.4. Device Description

The DePuy Synthes 2.4 mm LCP Volar Column Distal Radius Plates are part of the Synthes Locking Distal Radius System which is a system consisting of metallic bone fixation plates designed to treat fractures and osteotomies of the distal radius.

1.5. Indications for Use

The DePuy Synthes 2.4 mm LCP Volar Column Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures of and osteotomies of the distal radius and other small bones.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.4 mm LCP Volar Column Distal Radius Plates. 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 2.4 mm LCP Volar Column Distal Radius Plates 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 Locking Hand Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K092247 DePuy Synthes Locking Hand Plates

1.4. Device Description

The DePuy Synthes Locking Hand plates consist of 2.0 mm LCP Distal Ulna Plates and 1.5 mm/2.0 mm and 2.0 mm Rotation Correction Plates which offer both stainless steel and titanium plating options merging locking screw technology with conventional techniques. Locking screws provide the ability to create a fixed angle construct while utilizing familiar AO plating techniques. A fixed-angle construct provides improved fixation in osteopenic bone or multi fragment fractures where traditional screw purchase is compromised.

1.5. Indications for Use

The DePuy Synthes Locking Hand Plates are intended for fixation of fractures, osteotomies, non-unions, replantations and fusions of small bones and small bone fragments, 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 Locking Hand Plates. 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 Hand Plates 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 2.4 mm VA-LCP Two-Column Narrow Volar Distal Radius – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K092556 DePuy Synthes 2.4 mm VA-LCP Two-Column Narrow Volar Distal Radius

1.4. Device Description

The DePuy Synthes 2.4 mm V A-LCP Two-Column Narrow Volar Distal Radius Plates are metallic plates intended for treatment of various fracture modes of the distal radius. The plates incorporate variableangle locking hole technology and are available in versions composed of stainless steel and titanium.

1.5. Indications for Use

The DePuy Synthes 2.4 mm VA-LCP Two-Column Narrow Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.4 mm VA-LCP Two-Column Narrow Volar Distal Radius. 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 2.4 mm VA-LCP Two-Column Narrow Volar Distal Radius 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 2.4 mm / 2.7 mm Variable Angle LCP Forefoot/Midfoot System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K100776 DePuy Synthes 2.4 mm / 2.7 mm Variable Angle LCP Forefoot/Midfoot System

1.4. Device Description

The DePuy Synthes 2.4 / 2.7 mm Variable Angle LCP Forefoot / Midfoot System consists of anatomic and procedure specific plates, including 1st MTP Fusion, TMT Fusion, Opening Wedge Osteotomy, X and Straight Fusion, Navicular, Cuboid, and Mesh Plates, with variable angle locking screws and cortex screws to aid in reconstructive foot surgery. The system components are offered in versions composed of implant grade stainless steel and titanium alloy.

1.5. Indications for Use

The DePuy Synthes 2.4 mm / 2.7 mm VA-LCP Forefoot / Midfoot System is indicated for fixation of osteotomies, fusions, fractures, non unions, mal unions and replantations of small bones and small bone fragments in adult and adolescent (12- 21 years) patients, including the foot and ankle, and 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 2.4 mm/2.7 mm Variable Angle LCP Forefoot/Midfoot 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 2.4 mm/2.7 mm Variable Angle LCP Forefoot/Midfoot 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 2.4 mm VA-LCP Dorsal Distal Radius Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K102694 DePuy Synthes 2.4 mm VA-LCP Dorsal Distal Radius Plates

1.4. Device Description

The DePuy Synthes 2.4 mm Variable Angle LCP Distal Radius Plates are used with a range of 2.4 mm variable angle locking screws, 2.4 mm cortex screws, and 2.7 mm cortex screws. The dorsal plate has a pre-contoured design to fit along the dorsal radial column of the distal radius. These plates incorporated variable angle locking technology. There are a variety of plate types and they are available in 316L Stainless Steel and CP4 Titanium. The plates are offered in 5 basic shapes: 2-hole L-plate, a 3-hole L-plate, straight (radial column) plates, oblique plates and T -plates. The L-plates, T -plates, and oblique plates come in 3- and 5-hole lengths. The straight (radial column) plates come in 5- and 6- hole lengths. The 2-Hole L-plate, a 3-hole L-plate, and oblique plates are also offered in left and right-angled configurations

1.5. Indications for Use

The DePuy Synthes 2.4 mm LCP Distal Radius System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra:articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.
The 2.4 mm LCP Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

The DePuy Synthes 2.4 mm Variable Angle LCP Two-Column Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

The DePuy Synthes 2.4mm Variable Angle LCP Two-Column Narrow Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

The DePuy Synthes Variable Angle LCP Distal Radius System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

The DePuy Synthes Synthes Locking Distal Radius Plating System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

The DePuy Synthes Ti-15Mo Locking Distal Radius Plating System Distal System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.4 mm VA-LCP Dorsal Distal Radius Plates. 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 2.4 mm VA-LCP Dorsal Distal Radius Plates 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 Multiloc Proximal Humeral Nailing System – MR Conditional

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

Regulatory Class: Class II; 888.3020

Product Code(s): HSB

1.3. Predicate Device

K103002 DePuy Synthes Multiloc Proximal Humeral Nailing System

1.4. Device Description

The DePuy Synthes MultiLoc Proximal Humeral Nailing System consists of metallic rods and accessories which are intended for implantation in the medullary canal of the proximal humerus for the fixation of fractures.

The system features intramedullary nail devices, as well as 4.5 mm bone screw and end cap accessories. The nails are cannulated, are offered in 8.0 mm and 9.0 mm diameters, and 160 mm in overall length. The nail, screw, and end cap devices are composed of titanium alloy. The nails additionally feature a polymer inlay in the proximal end to enhance the stability of the 4.5 mm MultiLoc proximal locking screws. The 4.5 mm MultiLoc Screws which are used to facilitate the proximal locking of the nail construct can be interlocked with existing Synthes 3.5 mm Locking Screws to enhance the stability of the construct.

1.5. Indications for Use

The DePuy Synthes MultiLoc Proximal Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Multiloc Proximal Humeral 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 Multiloc Proximal Humeral 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 2.4 mm VA-LCP Intercarpal Fusion System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K103243 DePuy Synthes 2.4 mm VA-LCP Intercarpal Fusion System

1.4. Device Description

The DePuy Synthes 2.4 mm VA-LCP Intercarpal Fusion System features low profile circular plates. The plates are available in two sizes: ø15 mm (6 holes) and ø17 mm (7 holes). The plates each feature variable angle locking technology. The plates also feature K-wire holes for positioning and temporary fixation.

1.5. Indications for Use

The DePuy Synthes 2.4 mm V A-LCP Intercarpal Fusion System is indicated for fusion of small bones of the hand including: hamate, capitate, lunate, and triquetrum, for the revision of failed partial wrist fusions, and is indicated for use in patients suffering pain and/or loss of function due to: Osteoarthritis, Rheumatoid arthritis, Post-traumatic or degenerative wrist arthritis, Carpal instability.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.4 mm VA-LCP Intercarpal Fusion 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 2.4 mm VA-LCP Intercarpal Fusion 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 2.4 mm VA-LCP Volar Rim Distal Radius System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K110125 DePuy Synthes 2.4 mm VA-LCP Volar Rim Distal Radius System

1.4. Device Description

The DePuy Synthes 2.4 mm Variable Angle LCP Distal Radius Plates are used with a range of 2.4 mm variable angle locking screws, 2.4 mm cortex screws, and 2.7 mm cortex screws. These plates incorporate variable angle locking technology. The Variable Angle LCP Volar Rim Distal Radius Plates are designed as low profile plates, designed to minimize soft tissue irritation by featuring a low contoured plate profile with countersunk screws, rounded edges, and polished surfaces. The plates feature both variable angle locking screw holes in the head and shaft and elongated variable angle combination holes along the shaft only. The plates are offered in 6- and 7-hole head configurations each with two additional contourable wing tabs with screws holes to provide even greater variability in screw placement for additional fracture reduction.

1.5. Indications for Use

The DePuy Synthes 2.4 mm Variable Angle LCP Volar Rim Distal Radius Plates are indicated for fixation of complex intra- and extra-articular fractures of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intraarticular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.4 mm VA-LCP Volar Rim Distal Radius 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 2.4 mm VA-LCP Volar Rim Distal Radius 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: June 01, 2017

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1.2. Device

Name of Device: DePuy Synthes 3.5mm Low Profile Cortical Screw – MR Conditional

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II; 888.3040

Product Code(s): HWC

1.3. Predicate Device

K111230 DePuy Synthes 3.5mm Low Profile Cortical Screw

1.4. Device Description

The DePuy Synthes 3.5 mm Low Profile Cortical Screws are self-tapping, have either a stardrive or hex drive recess, are manufactured from stainless steel and titanium and offered both sterile and non sterile. The self-tapping screws are available in lengths ranging from 10 mm – 110 mm and may be used independently or with any Synthes plate which accepts Synthes 3.5 mm cortical screws. The low profile screw head is designed to minimize hardware prominence and the resultant potential for soft tissue irritation.

1.5. Indications for Use

The DePuy Synthes 3.5 mm Low Profile Cortical Screws are intended for fixation of ITactures, 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 the 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 3.5mm Low Profile Cortical 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 3.5mm Low Profile Cortical 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.

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1.2. Device

Name of Device: DePuy Synthes LCP Pediatric Plate Systems – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K112085 DePuy Synthes LCP Pediatric Plate Systems

1.4. Device Description

The DePuy Synthes system is a collection of plates used to treat fractures and osteotomies of the femur in infants, children, adolescents, and small statured adults. The complete system includes the following:

- 3.5mm and 5.0 mm plates with a 90° angle
- 2.7mm, 3.5mm and 5.0 mm plates with a 100° angle
- 2.7mm, 3.5mm and 5.0 mm plates with a 110° angle
- 3.5mm and 5.0 mm plates with a 120° angle
- 2.7mm, 3.5mm and 5.0 mm plates with a 130° angle
- 3.5mm and 5.0 mm plates with a 140° angle
- 3.5mm and 5.0 mm plates with a 150° angle

The system accepts existing cortical and locking screws, and features allows for both dynamic compression and locking through Combi holes. The plates are universally designed for both left and right use.

1.5. Indications for Use

The DePuy Synthes Pediatric LCP Plate System is indicated for fixation of fractures (including pathologic and impending pathologic fractures) and osteotomies of the femur in infants, children, adolescents and small statured adults.

Specific indications for the 100°, 120°, 130°, 140°, 150° plates include:

- Varus, valgus, rotational and/or shortening osteotomies
- Femoral neck and/or pertrochanteric fractures
- Proximal metaphyseal fractures
- Diaphyseal fractures
- Pathologic fractures
- Prophylactic use for impending pathologic fractures

Specific indications for the 90° plates include:

- Varus, valgus, rotational and/or shortening osteotomies
- Femoral neck and/or penrochanteric fractures
- Proximal and distal metaphyseal fractures
- Diaphyseal fractures
- Pathologic fractures
- Prophylactic usc for impending pathologic fractures

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes LCP Pediatric Plate Systems. 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 Pediatric Plate Systems 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 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 DePuy 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 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 subject 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 1.0 mm, 1.3 mm, 1.5 mm, 2.0 mm, and 2.4 mm 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 2.7 mm 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 Synthes 2.7 mm Cortex Screw may also be used in fusion applications in adults and adolescents (12-21 years) when used with the Synthes 2.4 mm / 2.7 mm Variable Angle LCP Forefoot/Midfoot System (K100776) and in adults and pediatric patients (2-12 years) when used with the Synthes Ti Wrist Fusion Plate (K023879).

The DePuy Synthes 3.5 mm and 4.0 mm 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 4.5 mm 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 2.7 mm LCP Ulna Osteotomy System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K113364 DePuy Synthes 2.7 mm LCP Ulna Osteotomy System

1.4. Device Description

The DePuy Synthes 2.7 mm LCP Ulna Osteotomy System consists of two plates, 6-hole and 8-hole which will be available in titanium alloy and stainless steel, to be offered sterile and non-sterile. This system also includes instrumentation which supports transverse and oblique osteotomy cuts as well as plate placement and fixation.

1.5. Indications for Use

The DePuy Synthes 2.7 mm LCP Ulna Osteotomy System is indicated for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, including osteopenic bone in the ulna. The 2.7 mm LCP Ulna Osteotomy System is indicated for use in both adults 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 2.7 mm LCP Ulna Osteotomy 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 2.7 mm LCP Ulna Osteotomy 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 3.5 mm VA-LCP Proximal Tibia Plate System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K120689 DePuy Synthes 3.5 mm VA-LCP Proximal Tibia Plate System

1.4. Device Description

The DePuy Synthes 3.5 mm VA-LCP Proximal Tibia Plate System consists of pre-contoured bone fixation plates intended for the treatment of fractures of the proximal tibia. Variable angle screws can be angled up to 15 degrees from the normal trajectory prior to locking the screw to the plate. Percutaneous instrumentation will allow the variable angle plates and screws to be applied through minimally invasive techniques.

1.5. Indications for Use

The DePuy Synthes 3.5 mm VA-LCP Proximal Tibia Plates are intended to treat fractures of the proximal tibia in adults and adolescents in which the growth plates have fused including: simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures. Plates can also be used for treatment of nonunions, mal unions, tibial osteotomies and 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 VA-LCP Proximal Tibia Plate 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 3.5 mm VA-LCP Proximal Tibia Plate 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 Multiloc Humeral Nailing System – MR Conditional

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

Regulatory Class: Class II; 888.3020

Product Code(s): HSB

1.3. Predicate Device

K120807 DePuy Synthes Multiloc Humeral Nailing System

1.4. Device Description

The DePuy Synthes MultiLoc Humeral Nailing System consists of metallic rods and accessories which are intended for implantation in the medullary canal of the humerus for fracture fixation. The system features intramedullary nail devices, as wen as bone screws and end cap accessories. The nails are cannulated, offered in 7.0 mm, 8.5 mm, and 10 mm diameters, and are available in 180 mm-315 mm in overall length. The nails additionally feature a polymer inlay in the proximal end to enhance the stability of the 4.5mm MultiLoc locking screws. Cleared 4.5 mm MultiLoc Screws, used to facilitate the proximal locking ofthe nail construct, can be interlocked with cleared Synthes 3.5 mm Locking Screws to enhance the stability of the construct.

1.5. Indications for Use

The DePuy Synthes MultiLoc Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal humeral fractures with diaphyseal extension, diaphyseal fractures of the humeral shaft, and impending pathologic humeral fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Multiloc Humeral 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 Multiloc Humeral 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 VA LCP Ankle Trauma System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K120854 DePuy Synthes VA LCP Ankle Trauma System

1.4. Device Description

The DePuy Synthes Variable Angle LCP Ankle Trauma System contains plates that are intended to treat fractures of the ankle, and includes multiple plate types to accommodate different fracture patterns and patient anatomy. Two screw configurations are included in the Synthes Variable Angle LCP Ankle Trauma System; 2.7 mm metaphyseal screws and 3.5 mm VA Locking Screws. Specifically, the following plates and screws are included in the Synthes Variable Angle LCP Ankle Trauma System:

- Medial and Anteromedial Distal Tibia Plates
- Distal Tibia T Plates and Distal Tibia L Plates
- Lateral Distal Fibula plate
- 2.7mm Metaphyseal Screws
- 3.5mm VA Locking Screws

All of the plates will be offered in both stainless steel and titanium alloy (TAN), and in both sterile and non-sterile configurations. All of the plate configurations (with the exception of the Distal Tibia T plate, which is symmetrical), will be offered in left and right designs. The system accepts existing cortical and locking screws (i.e. K000684 and K043185) as well as 3.5 mm VA Locking Screws and 2.7 mm Metaphyseal Screws, and allows for both dynamic compression and locking through Combi holes.

1.5. Indications for Use

The DePuy Synthes Variable Angle LCP Ankle Trauma System is intended for fixation of the ankle in adults and adolescents (12-21) in which the growth plates have fused, and particularly in osteopenic bone. Specifically,

- Medial and Anteromedial Distal Tibia Plates are intended for fixation of osteotomies, fractures, non unions, mal unions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,
- Distal Tibia T Plates and Distal Tibia L Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia, and
- Lateral Distal Fibula Plates are intended for fixation of osteotomies, fractures, non unions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes VA LCP Ankle Trauma 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 VA LCP Ankle Trauma 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 2.7/3.5 mm Variable Angle LCP Ankle Trauma System-Anterolateral Distal Tibia Plate – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K121601 DePuy Synthes 2.7/3.5 mm Variable Angle LCP Ankle Trauma System-Anterolateral Distal Tibia Plate

1.4. Device Description

The DePuy Synthes Anterolateral Distal Tibia Plates are intended to treat fractures of the distal tibia. The Anterolateral Distal Tibia Plates and 3.5 mm VA Locking Screws are offered in both stainless steel and titanium alloy (TAN), and in both sterile and non-sterile configurations. The Anterolateral Distal Tibia Plates will be offered in left and right configurations.

The system accepts existing cortical screws, locking screws, dynamic locking screws, and metaphyseal screws as well as 3.5 mm VA Locking Screws, and allows for both dynamic compression and locking through Combi holes.

1.5. Indications for Use

The DePuy Synthes 2.7/3.5 mm Variable Angle LCP Ankle Trauma System is intended Indications for Use for fixation of the ankle and is indicated in adults and adolescents (12-21) in which the growth plates have fused, and particularly in osteopenic bone.
Specifically,

- Anterolateral Distal Tibia Plates are intended for fixation of osteotomies, fractures, non unions, mal unions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia.
- Medial and Anteromedial Distal Tibia Plates are intended for fixation of osteotomies, fractures, non unions, mal unions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,
- Distal Tibia T Plates and Distal Tibia L Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia, and
- Lateral Distal Fibula Plates are intended for fixation of osteotomies, fractures, nonunions, mal unions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.7/3.5 mm Variable Angle LCP Ankle Trauma System-Anterolateral Distal Tibia Plate. 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 2.7/3.5 mm Variable Angle LCP Ankle Trauma System-Anterolateral Distal Tibia Plate 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 2.7 mm and 3.5 mm Variable Angle LCP Midfoot/Hindfoot System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K131186 DePuy Synthes 2.7 mm and 3.5 mm Variable Angle LCP Midfoot/Hindfoot System

1.4. Device Description

The DePuy Synthes 2.7 mm and 3.5 mm Variable Angle LCP Midfoot/Hindfoot System is a collection of plates used for fixation of fractures of the foot and, ankle in adults and adolescents (12-21) in which the growth plates have fused or in which the growth plates will not be crossed by the plate system. The complete system includes the following plate types:

- 2.4mm/2.7mm Variable Angle Locking Talus Plate
- 2.7mm Variable Angle Locking Calcaneal Plate
- 2.7mm Variable Angle Locking Anterolateral Calcaneal Plate
- 3.5mm Variable Angle Locking Compression Medial Column Fusion Plate

The system accepts various screw fixation options such as existing cortical, locking, variable angle locking, low profile, cannulated locking, cannulated conical and metaphyseal screws. The

plates are low profile in design and offered in variations of Stainless Steel, Commercially Pure Titanium-Grade 4, and Titanium Alloy (TAN). When used in conjunction with a plate system, the system mdications apply to the entire construct. including the screws .

1.5. Indications for Use

The DePuy Synthes 2.7 mm and 3.5 mm Variable Angle LCP Midfoot/Hindfoot System is indicated for fixation of osteotomie, fusions, fractures, nonunions, malunions and replantations of small bones and small one fragments in adult and adolescent (12 -21 years) patients, including the foot and ankle, and particularly in osteopenic bone.

The DePuy Synthes 3.5 mm Low Profile Cortical Screws and the Synthes 3.5 mm Cortex Screws are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, hand, radius, ulna, pelvis, tibia, femur, fibula, 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 the 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 2.7 mm and 3.5 mm Variable Angle LCP Midfoot/Hindfoot 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 2.7 mm and 3.5 mm Variable Angle LCP Midfoot/Hindfoot 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 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 – MR Conditional

Classification Name(s): Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II; 888.3040

Product Code(s): HWC, HRS, HTN

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

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; 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 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. 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 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: June 01, 2017

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Condylar Buttress Plates – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K162124 DePuy Synthes Condylar Buttress Plates

1.4. Device Description

The DePuy Synthes 4.5 mm VA LCP Curved Condylar Plate System consists of anatomically-contoured, stainless steel and titanium plates and screws featuring variable angle locking and combi-holes designed to provide stable fixation of the distal femur and system specific instrumentation. The current 510(k) introduces OPTILINK™ Technology stainless steel screws, positioning pins for cerclage cable, and system specific instrumentation as a line extension to the currently cleared Synthes 4.5 mm VA LCP Curved Condylar Plate System.

1.5. Indications for Use

The DePuy Synthes Variable Angle Positioning Pins are intended for use with cerclage multifilament cable to augment fracture stabilization with plates used in long bone fixation, when screw placement would be inhibited, as in the presence of intramedullary implant. The Variable Angle Positioning Pins are designed for use with Variable Angle LCP plate implants featuring variable angle locking holes that accept 5.0 mm variable angle bone screws.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Condylar Buttress Plates. 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 Condylar Buttress Plates 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 Angled Blade Plate – MR Conditional

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

Regulatory Class: Class II; 888.3030

Product Code(s): KTW, HRS

1.3. Predicate Device

K914546 DePuy Synthes Angled Blade Plate

1.4. Device Description

The DePuy Synthes Angled Blade Plates are manufactured from 316L stainless steel. The plates are of various angles and offsets to accomodate specific surgical application, and are attached with stainless steel screws.

1.5. Indications for Use

The DePuy Synthes Angled Blade Plate is intended for use in femoral fractures and osteotomies. More specifically, the primary intended uses are as follows:

- fractures of the distal and proximal femur
- femoral neck and pertrochanteric fractures
- intertrochanteric femoral osteotomies
- repositioning osteotomy (femoral neck)

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Angled Blade Plate. 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 Angled Blade Plate 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 Unreamed Humeral Nail (URHN) – MR Conditional

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

Regulatory Class: Class II; 888.3020

Product Code(s): HSB

1.3. Predicate Device

K933518 DePuy Synthes Unreamed Humeral Nail (URHN)

1.4. Device Description

The DePuy Synthes 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.

1.5. Indications for Use

The DePuy Synthes Unreamed Humeral Nail (URHN) is generally indicated for Humeral shaft fractures. Specifically,

- Acute humeral shaft fractures;
- Pathologic or impending pathologic fractures;
- Non and malunions 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 Elastic Intramedullary Nail (EIN) System – MR Conditional

Classification Name(s): Pin, Fixation, Smooth

Regulatory Class: Class II; 888.3040

Product Code(s): HTY

1.3. Predicate Device

K971783 DePuy Synthes Elastic Intramedullary Nail (EIN) System

1.4. Device Description

The DePuy Synthes EIN 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 EIN 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.

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1.2. Device

Name of Device: DePuy Synthes Distal Radius Plate System (DRPS) – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K982732 DePuy Synthes Distal Radius Plate System (DRPS)

1.4. Device Description

The DePuy Synthes Distal Radius Plate System consists of volar and dorsal plates, 2.4 mm cortex screws, and 1.8 mm threaded-head buttress pins. The volar plate is T-shaped, with the head 18° from perpendicular to the shaft; it is precontoured with a 20° bend near the head and has six threaded screw holes that are angled 10° proximally. The dorsal plate is shaped like the Greek letter Pi, with two proximal legs (shaft) and one distal arm (head); it is precontoured, and has six internally threaded screw holes in the head. The heads of both plates have a 30° ramp added to the proximal (volar plate) and distal (dorsal plate) sides. The shafts of both plates have a 45° chamfer and compression screw holes. Both plates are available in right and left versions; accept cortex screws (2.7 mm and 2.4 mm) and 1.8 mm threaded-head buttress pins; and can be cut to size.

1.5. Indications for Use

The DePuy Synthes Distal Radius Plate System is intended for fixation of fractures, osteotomies, including carpal fusions involving the distal radius applied to the volar and dorsal aspect.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Distal Radius Plate System (DRPS). 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 Distal Radius Plate System (DRPS) 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 Calcaneal Plates – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II; 888.3030

Product Code(s): HRS

1.3. Predicate Device

K991407 DePuy Synthes Calcaneal Plates

1.4. Device Description

The DePuy Synthes LCPs are designed to address complex fractures of the calcaneus and are applied to the lateral side. The plate has 15 threaded screw holes, which accept 2.7 mm and 3.5 mm cortex screws, as well as 3.0 mm locking screws. The plates are available for right and left placements.

1.5. Indications for Use

The DePuy Synthes Locking Calcaneal Plates are indicated for fractures and osteotomies of the calcaneus, including, but not limited to extra-articular, intra-articular, joint depression, tongue type and severely comminuted fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Calcaneal Plates. 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 Calcaneal Plates 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 Spiral Blade for Humeral Nail (SBHN) – MR Conditional

Classification Name(s): Nail, Fixation, Bone

Regulatory Class: Class II; 888.3030

Product Code(s): JDS

1.3. Predicate Device

K992348 DePuy Synthes Spiral Blade for Humeral Nail (SBHN)

1.4. Device Description

The DePuy Synthes Spiral Blade for Humerus Nail is used in conjunction with Synthes Unreamed Humeral Nail to stabilize fractures of the humerus. The SBHN is available in lengths ranging from 34 mm to 54 mm in 2 mm increments. A Locking End Cap is used to lock the Spiral Blade in place. The Locking End Cap has a 5 mm extension.

1.5. Indications for Use

The DePuy Synthes Spiral Blade for Humeral Nail 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.

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1.2. Device

Name of Device: DePuy Synthes Kirschner (K-) Wires and Guide Wires – MR Conditional

Classification Name(s): Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II; 888.3040

Product Code(s): HTY, LRN, LXT, JDW

1.3. Reference Device

K161489 Syntorr K-Wire and Pin System

1.4. Device Description

The DePuy Synthes K-Wires are used 1) with Synthes External Fixators and Lengthening Apparatus; 2) as an intraoperative reduction/stabilization tool; 3) for percutaneous fixation of fractures; and 4) as a guide for screws and drill bits. The K-wires are straight wires with a trocar tip on one or both ends and are available in various diameters and lengths.

The DePuy Synthes Guide Wires are straight wires with a point on one or both ends and are available in various diameters and lengths. They are used to reduce and stabilize bone fractures. The wires can also be used as a guide for cannulated implants.

1.5. Indications for Use

The DePuy Synthes Kirschner (K-) Wires and Guide Wires are indicated for use in open and percutaneous fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants, for implantation through the skin, and as traction pins so that traction may be applied to the skeletal system.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Kirschner (K-) Wires and Guide Wires. 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 Kirschner (K-) Wires and Guide Wires 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.