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

November 1, 2018

Re: K180310
Trade/Device Name: DePuy Synthes Trauma Orthopedic Plates and Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, KTT, KTW, LXT
Dated: September 28, 2018
Received: October 1, 2018

Dear Jeffrey Krawiec:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2018.11.01 18:42:03 -04'00'

For:
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes Reconstructive Plates 'Y' Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Reconstructive Plates 'Y' Plates are indicated for pelvic and acetabular reconstructive surgery and the reduction of fractures in the distal humerus, the clavicle, and the scapula.

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

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510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes Anatomical Locking Plate System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Anatomical Locking Plate System is indicated to treat fractures (including but not limited to) the radius, ulna, humerus, tibia, fibula, 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)*
K180310

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

Indications for Use *(Describe)*
The DePuy Synthes CABP System is a plate and screw system intended to treat fractures of the proximal humerus and distal tibia.

Proximal humerus fractures include two-part greater tubercle fractures and fracture dislocations, two-part surgical neck fractures and fracture dislocations, three-part fractures or fracture dislocations, fractures in osteopenic bone, and nonunions and malunions.

Distal tibia fractures include acute fractures, fractures in osteopenic bone, and nonunions and malunions.

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

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

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510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes 3.5 mm 90° Cannulated Limited Contact-Angled Blade Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm 90° Cannulated Limited Contact Angled Blade Plates are intended for the fixation of fractures and non-unions of the proximal humerus and distal tibia.

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

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

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510(k) Number *(if known)*
K180310

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. 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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510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes Large Fragment Locking Compression Plate (LCP) System - T Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Large Fragment Locking Compression Plate (LCP) System - T Plate is 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)*
K180310

Device Name
DePuy Synthes Curved Reconstruction Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Curved Reconstruction 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)*
K180310

Device Name
DePuy Synthes One-Third Tubular Dynamic Compression Locking (DCL) Plate – 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)*
K180310

Device Name
DePuy Synthes LCP Proximal Humerus Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Proximal Humerus Plate is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, 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)*
K180310

Device Name
DePuy Synthes Pilon Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Pilon Plate is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia.

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

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

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510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes TomoFix Osteotomy System – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes TomoFix Osteotomy System is intended for open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia and lateral distal femur, treatment of bone and joint deformities, and malalignment caused by injury or disease such as osteoarthritis.

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)*
K180310

Device Name
DePuy Synthes 3.5 mm Broad LCP & 4.5 mm LCP Distal Humerus Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm Broad LCP & 4.5 mm LCP Distal Humerus Plates are indicated for fractures of the distal humerus.

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

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

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510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes Clavicle Hook Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Clavicle Hook Plate is intended for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

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

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

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510(k) Number *(if known)*
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Device Name
DePuy Synthes 3.5 / 4.5 mm LCP® Metaphyseal Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 / 4.5 LCP Metaphyseal Plate is intended for fixation of various long bones, excluding the femur. It is also for use in fixation of osteopenic bone and fixation of nonunions or malunions.

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

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

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510(k) Number *(if known)*
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Device Name
DePuy Synthes 3.5 mm LCP Distal Humerus System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm LCP Distal Humerus System is indicated for intraarticular fractures of the distal humerus, commninuted supra-condylar fractures, osteotomies, and non-unions of the distal 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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K180310

Device Name
DePuy Synthes LCP® Proximal Humerus Plates, Long – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Proximal Humerus Plate, Long is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, 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)*
K180310

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)*

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes Low Profile Reconstruction Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Low Profile Reconstruction Plates are intended for pelvic and acetabular reconstruction and fixation of fractures of the distal humerus, clavicle, and scapula.

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

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

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Indications for Use

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

510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes 3.5 mm Spring Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm Spring Plate is intended for pelvic and acetabular reconstructive surgery and fracture fixation 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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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes 3.5 mm LCP Hook Plate – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm LCP Hook Plate is indicated for fractures, osteotomies and non-unions of small bones including the ulna, radius, tibia and fibula, particularly in osteopenic bone.

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

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

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See PRA Statement below.

510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes 3.5mm LCP Periarticular Proximal Humerus Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm LCP Periarticular Proximal Humerus Plates are indicated for fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus, 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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See PRA Statement below.

510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm Locking Compression Plate (LCP) System:

The DePuy Synthes 3.5 mm LCP is indicated for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, 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 (LCP) System:

The DePuy Synthes 4.5 mm LCP is indicated for fixation of various 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 fixation 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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

510(k) Number *(if known)*
K180310

Device Name
DePuy Synthes 3.5 mm Locking Attachment Plates – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5mm Locking Attachment Plate is intended for use with DePuy Synthes LCP plates to augment the stabilization of fractures, including periprosthetic fractures and fractures in the presence of intramedullary implants, in the femur, tibia and humerus, 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)*
K180310

Device Name
DePuy Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm Curved Narrow and Broad LCP Plates are intended for fixation of fractures, osteotomies and non-unions of clavicle, scapula, olecranon, humerus, radius, pelvis, distal tibia and fibula, particularly in osteopenic bone for adult patients.

The DePuy Synthes 4.5 mm Curved Narrow and Broad LCP Plates are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of periprosthetic fractures, osteopenic bone, and non-unions or malunions in adult patients.

The DePuy Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad LCP Plates are also indicated for fracture fixation 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)*
K180310

Device Name
DePuy Synthes 2.7 mm / 3.5 mm VA-LCP Anterior Clavicle Plate System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.7 mm / 3.5 mm VA-LCP Anterior Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate 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)*
K180310

Device Name
DePuy Synthes 3.5 mm LCP Clavicle Plate System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm LCP Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which clavicular growth plates have fused or in which the growth plates will not be crossed by the plate 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)*
K180310

Device Name
DePuy Synthes Variable Angle LCP Elbow System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Variable Angle LCP Elbow System is intended for fixation of fractures of the distal humerus, olecranon and ulna 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. Specifically,

- Distal humerus plates are indicated for intra-articular fractures, commninuted supracondylar fractures, osteotomies, malunions and non-unions of the distal humerus.

- Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.

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)*
K180310

Device Name
DePuy Synthes Variable Angle LCP Elbow System (Medial and Posterolateral Distal Humerus Plates) – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Variable Angle LCP Elbow System is intended for fixation of fractures of the distal humerus, olecranon and ulna in adults and adolescents (12-2 1) in which the growth plates have fused. Specifically,

• Distal humerus plates are indicated for intra-articular fractures, comminuted supracondylar fractures, osteotomies, malunions and non-unions of the distal humerus.

• Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.

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)*
K180310

Device Name
DePuy Synthes TOMOFIX Osteotomy System – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes TOMOFIX Osteotomy System is intended for osteotomies, treatment of bone and joint deformities, fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur and proximal tibia.

Specifically,
-The TOMOFIX Medial Proximal Tibia Plates are indicated for open- and close-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the medial proximal tibia

-The TOMOFIX Lateral Proximal Tibia Plates are indicated for open- and closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the lateral proximal tibia

-The TOMOFIX Lateral Distal Femur Plates are indicated for open- and closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the lateral distal femur

-The TOMOFIX Medial Distal Femur Plates are indicated for closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the medial distal 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)*
K180310

Device Name
DePuy Synthes 2.4/2.7mm VA LCP Two-Column Volar Distal Radius Plate, Extra-Long - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 2.4/2.7 mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long is intended for intra- and extra-articular fractures, osteotomies, nonunions and malunions of the distal radius, with or without extension into the radial diaphysis in adults and adolescents (12-21) where the growth plates have fused or will not be crossed, and the following adolescent distal radius fractures:

- Intra-articular fractures exiting the epiphysis
- Intra-articular fractures exiting the metaphysis
- Physeal crush injuries
- 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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510(k) Summary

Date Prepared: October 29, 2018

1.1 Submitter

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1.2. Device

Name of Device: DePuy Synthes Reconstructive Plates 'Y' Plates – MR Conditional

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

Regulatory Class: Class II, §888.3030

Product Code(s): KTW

1.3. Predicate Device

K792291 Synthes Reconstructive Plates 'Y' Plates

1.4. Device Description

The 3.5 mm Reconstruction Plate is available in multiple lengths. It has a smooth underside, is notched between the screw holes and can be adjusted (contoured) in three dimensions. The screw holes are designed to provide limited bidirectional compression of the fracture via the tapered entrance of the hole, and accept 3.5 mm cortex screws

The 4.5 mm Reconstruction Plate has a smooth underside, is notched between the screw holes and can be adjusted (contoured) in three dimensions. The oval holes are designed to provide limited bidirectional compression of the fracture via the tapered entrance of the hole which allows 25° longitudinal and 7° lateral angulation of screws. It is available in multiple lengths and accepts 4.5 mm cortex and 6.5 mm cancellous screws.

The 3.5 mm Curved Reconstruction Plate is available in multiple lengths. It has a smooth underside and is notched between screw holes and can be adjusted (contoured) in three dimensions. The screw holes are designed to provide limited bidirectional compression of the fracture via the tapered entrance of the hole and accept 3.5 mm cortex screws.

1.5. Intended Use

The DePuy Synthes Reconstructive Plates 'Y' Plates are indicated for pelvic and acetabular reconstructive surgery and the reduction of fractures in the distal humerus, the clavicle, and the scapula.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Reconstructive Plates 'Y' 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 Reconstructive Plates 'Y' 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.

DePuy Synthes People inspired™
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510(k) Summary

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1.2. Device

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

Classification Name(s): Screw, Fixation, Bone

Regulatory Class: Class II, §888.3040

Product Code(s): HWC, HRS

1.3. Predicate Device

K961413 Synthes Anatomical Locking Plate System

1.4. Device Description

The Anatomical Locking Plate System utilizes a locking feature that secures the screw to the plate, enabling stable fixation to be achieved via unicortical or bicortical fixation. The plates are available with and without an anatomically contoured head, in a variety of sizes. The head of the screw has a round cross section with a conical underside to fit into the plate. The underside has a tapered thread to match the design of the holes in the plate. The screws are available in thread diameters from 3 mm to 5 mm, in a variety of lengths.

1.5. Intended Use

The DePuy Synthes Anatomical Locking Plate System indicated to treat fractures (including but not limited to) the radius, ulna, humerus, tibia, fibula, femur.

1.6. Substantial Equivalence

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

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Anatomical Locking Plate System 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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510(k) Summary

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tshea@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Cannulated Angle Blade Plate (CABP) System – MR Conditional

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

Regulatory Class: Class II, §888.3030

Product Code(s): KTT

1.3. Predicate Device

K974537 Synthes Cannulated Angle Blade Plate (CABP) System

1.4. Device Description

The CABP is a straight plate with a blade at the head to allow for better fixation in the head of the humerus or in the distal tibia. The blade of the plate is cannulated to fit over a guide wire, allowing for the adjustment of the wire placement several times without adversely affecting the final result. There are cuts in the undersurface of the plate to reduce the surface area of the plate in contact with bone. The area of contact between the plate and the bone is decreased in an effort to reduce damage to the cortical blood supply under the plat, and resultant reduction in damage-induced porosis and remodeling of the bone near the plate undersurface. Plate undercuts also make the bending properties of the plate more uniform, which facilitate contouring. The plate has round and dynamic compression screw

holes, accepts 4.5mm and 6.5 mm screws, is available in multiple blade lengths, and is manufactured from stainless steel and commercially pure titanium.

1.5. Intended Use

The DePuy Synthes CABP System is a plate and screw system intended to treat fractures of the proximal humerus and distal tibia.

Proximal humerus fractures include two-part greater tubercle fractures and fracture dislocations, two-part surgical neck fractures and fracture dislocations, three-part fractures or fracture dislocations, fractures in osteopenic bone, and nonunions and malunions.

Distal tibia fractures include acute fractures, fractures in osteopenic bone, and nonunions and malunions.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Cannulated Angle Blade Plate (CABP) System. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Cannulated Angle Blade Plate (CABP) 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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510(k) Summary

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1.2. Device

Name of Device: DePuy Synthes 3.5 mm 90° Cannulated Limited Contact-Angled Blade Plates – MR Conditional

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

Regulatory Class: Class II, §888.3030

Product Code(s): KTW

1.3. Predicate Device

K992837 Synthes 3.5 mm 90° Cannulated Limited Contact-Angled Blade Plates

1.4. Device Description

The DePuy Synthes 3.5 mm 90° Cannulated LC-ABP provides stable fracture fixation and rotational control for fractures of the proximal humerus and distal tibia. The plates feature a low profile limited contact dynamic compression plate (LC-DCP®) design and dynamic compression unit (DCU) screw holes. The blade portion of the plate is cannulated to accept a 2.0 mm guide wire. The plates are available in various sizes to accommodate varying patient anatomy.

1.5. Intended Use

The DePuy Synthes 3.5 mm 90° Cannulated Limited Contact Angled Blade Plates are intended for the fixation of fractures and non-unions of the proximal humerus and distal tibia.

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 90° Cannulated Limited Contact-Angled Blade 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 3.5 mm 90° Cannulated Limited Contact-Angled Blade 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 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

1.3. Predicate Device

K000682 Synthes Large Fragment Dynamic Compression Locking (DCL) System

1.4. Device Description

The 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. Intended Use

The DePuy Synthes Large Fragment DCL is intended for fixation of various long bones, such as the humerus, femur and tibia. 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.

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1.2. Device

Name of Device: DePuy Synthes Large Fragment Locking Compression Plate (LCP) System - T Plate – 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

K010766 Synthes (USA) Large Fragment Locking Compression Plate (LCP) System - T Plate

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. Intended Use

The DePuy Synthes Large Fragment Locking Compression Plate (LCP) System - T Plate is 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 (USA) Large Fragment Locking Compression Plate (LCP) System - T 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 (USA) Large Fragment Locking Compression Plate (LCP) System - T 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 Curved Reconstruction Plate – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K011334 Synthes Curved Reconstruction Plate

1.4. Device Description

The DePuy Synthes Curved Reconstruction Plate line extension is a pre-curved version of the currently marketed Straight Locking Reconstruction Plate. Both of these plates will be included as part of the DePuy Synthes Small Fragment DCL System. Both the curved and straight plates have the same intended use and there is no change in safety or efficacy.

1.5. Intended Use

The DePuy Synthes Curved Reconstruction 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 Curved Reconstruction 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 Curved Reconstruction 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 One-Third Tubular Dynamic Compression Locking (DCL) Plate – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K011335 Synthes One-third DCL Plate

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 Small Fragment DCL System. The new plates have the same intended use as other plates in the system and there is no change in safety or efficacy.

1.5. Intended 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 DCL 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 One-third DCL 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 LCP Proximal Humerus Plate – MR Conditional

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

Regulatory Class: Class II, §888.3030

Product Code(s): KTW

1.3. Predicate Device

K011815 Synthes LCP Proximal Humerus Plate

1.4. Device Description

The DePuy Synthes LCP Proximal Humerus Plates are designed to match the anatomy of the proximal humerus. These plates can be applied to either the right or left humerus. The proximal portion of each plate has threaded holes that accept 3.5 mm or 2.7 mm screws. The distal portion of the plate has combination holes that allow the option of using 3.5 mm locking or cortex screws, or 4.0 mm cancellous screws to accomplish plate fixation. These plates will be offered as an addition to the DePuy Synthes Small Fragment LCP (formerly DCL) System.

1.5. Intended Use

The DePuy Synthes LCP Proximal Humerus Plate is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, 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 LCP Proximal Humerus 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 LCP Proximal Humerus 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 Pilon Plate – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K020602 Synthes Pilon Plate

1.4. Device Description

The DePuy Synthes Pilon Plate is a metal plate that offers screw to plate locking designed for various fracture modes of the distal end of the tibia.

1.5. Intended Use

The DePuy Synthes Pilon Plate is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for DePuy Synthes Pilon 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 Pilon 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 TomoFix™ Osteotomy 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

K023941 Synthes TomoFix™ Osteotomy System

1.4. Device Description

The TomoFix™ Osteotomy System consists of five different titanium plates with locking and combination holes. There are two plates (left and right) for the lateral distal femur, 2 plates (left and right) for the lateral proximal tibia, and 1 plate for the medial proximal tibia.

1.5. Intended Use

The DePuy Synthes TomoFix™ Osteotomy System is intended for open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia and lateral distal femur, treatment of bone and joint deformities, and malalignment caused by injury or disease such as osteoarthritis.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes TomoFix™ 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 TomoFix™ 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 Broad LCP & 4.5 mm LCP Distal Humerus Plate – MR Conditional

Classification Name(s): Plate, Fixation, Bone.

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K031178 3.5 mm Broad LCP & 4.5 mm LCP Distal Humerus Plate

1.4. Device Description

The DePuy Synthes 3.5 mm Broad LCP & 4.5 mm Broad LCP Distal Humerus Plates are contoured to match the anatomy of the distal humerus with a limited contact low profile design. The plate has dynamic compression holes combined with locking holes which accept 3.5 & 4.5 mm cortex, 3.5 & 4.5 mm self-tapping cortex, 3.5 mm shaft, 3.5,4.0, & 5.0 mm locking, and 4.0 mm cancellous screws. The plates are available in various lengths.

1.5. Intended Use

The DePuy Synthes 3.5 mm Broad LCP & 4.5 mm LCP Distal Humerus Plates are indicated for fractures of the distal humerus.

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 Broad LCP & 4.5 mm LCP Distal Humerus 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 3.5 mm Broad LCP & 4.5 mm LCP Distal Humerus 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 Clavicle Hook Plate – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K031677 Synthes (USA) Clavicle Hook Plate

1.4. Device Description

The DePuy Synthes Clavicle Hook Plate is an anatomically designed L-shaped plate featuring a distal joint bridging hook with a rounded end. The shaft of the plate contains either dynamic compression screw holes or LCP plate holes. The plates accept 3.5 mm cortex, 4.0 mm cancellous and 3.5 mm locking screws (LCP Clavicle Hook Plate only).

1.5. Intended Use

The DePuy Synthes Clavicle Hook Plate is intended for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Clavicle 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 Clavicle 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 3.5 / 4.5 mm LCP® Metaphyseal Plates – MR Conditional

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

Regulatory Class: Class II, §888.3030

Product Code(s): LXT

1.3. Predicate Device

K033805 Synthes (USA) 3.5 / 4.5 mm LCP® Metaphyseal Plates

1.4. Device Description

The DePuy Synthes 3.5 / 4.5 mm LCP® Metaphyseal Plates are contourable to match the anatomy, have a limited contact design, and are tapered at the plate head. The 3.5 / 4.5 mm metaphyseal plates feature combination dynamic compression / locking screws holes (combi-holes). The plates in this system accept 3.5 / 4.5 mm cortex, 3.5, 4.0, & 5.0 mm locking, and 4.0 mm or 6.5 mm cancellous screws. The plate also has a 2.0 mm hole for preliminary fixation with k-wires.

1.5. Intended Use

The DePuy Synthes 3.5 / 4.5mm LCP® Metaphyseal Plate is intended for the fixation of various long bones, excluding the femur. It is also for use in fixation of osteopenic bone and fixation of nonunions or malunions.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 3.5 / 4.5 mm LCP® Metaphyseal 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 3.5 / 4.5 mm LCP® Metaphyseal 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 3.5 mm LCP Distal Humerus System – MR Conditional

Classification Name(s): Single/Multiple component metallic bone fixation appliances and accessories. And Smooth/threaded metallic bone fixation fastener

Regulatory Class: Class II, §888.3030 and §888.3040

Product Code(s): KTT

1.3. Predicate Device

K033995 3.5 mm LCP Distal Humerus System

1.4. Device Description

The DePuy Synthes 3.5 mm LCP Distal Humerus System consists of medial and postero-lateral distal humerus plates of various lengths and 2.7 mm locking screws. The plates are pre-contoured to match the anatomy of the distal humerus with a limited contact low profile design. The plate features locking compression holes and conical locking holes which accept 2.4, 3.5, & 4.0 mm cortex screws, 2.4, 2.7 & 3.5 mm locking screws, and 4.0 mm cancellous screws. The System will be available in Stainless Steel and Titanium.

1.5. Intended Use

The DePuy Synthes 3.5 mm LCP Distal Humerus System is indicated for intraarticular fractures of the distal humerus, commninuted supra-condylar fractures, osteotomies, and non-unions of the distal humerus.

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 LCP Distal Humerus 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 LCP Distal Humerus 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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510(k) Summary

Date Prepared: October 29, 2018

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1.2. Device

Name of Device: DePuy Synthes LCP® Proximal Humerus Plates, Long – MR Conditional

Classification Name(s): Single/Multiple component metallic bone fixation appliances and accessories.

Regulatory Class: Class II, §888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K041860 Synthes (USA) LCP® Proximal Humerus Plates, Long

1.4. Device Description

The DePuy Synthes LCP Proximal Humerus Plates, long are pre-contoured to match the anatomy of the proximal humerus with a limited contact low profile design. The plate features locking holes and combination locking and compression holes which accept 2.7, 3.5, & 4.0 mm cortex screws, 3.5 mm locking screws, and 4.0 mm cancellous screws. The System will be available in Stainless Steel and Titanium. These plates will be offered as an addition to the DePuy Synthes Small Fragment LCP (formerly DCL) System.

1.5. Intended Use

The DePuy Synthes LCP Proximal Humerus Plate, Long is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, 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 LCP® Proximal Humerus Plates, Long. 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® Proximal Humerus Plates, Long 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 metallic bone fixation appliances and accessories.

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K041911 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. Intended 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 LCP® Curved 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® Curved 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 Low Profile Reconstruction Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K042377 Synthes Low Profile Reconstruction Plates

1.4. Device Description

The DePuy Synthes 3.5 mm Low Profile Reconstruction Plates consist of straight, curved, and J-shaped plates. The shape and profile of these plates are designed to minimize soft tissue irritation and minimize the need for intraoperative contouring. However, when intraoperative contouring is required for a precise fit with the bone, the plate design allows for simple and uniform bending.

1.5. Intended Use

The DePuy Synthes Low Profile Reconstruction Plates are intended for pelvic and acetabular reconstruction and fixation of fractures of the distal humerus, clavicle, and scapula.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for DePuy Synthes Low Profile Reconstruction 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 Low Profile Reconstruction 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 3.5 mm Spring Plate – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K061973 Synthes 3.5 mm Spring Plate

1.4. Device Description

The DePuy Synthes 3.5mm Spring Plate is a variation of the DePuy Synthes one-third tubular plate with collar which utilizes two sharp spikes at the bottom surface and a pre-bent convex shape to aid in the reduction of small bone fragments while conforming to bony uneven surfaces. The plate incorporates a 1 - 10 hole design in lengths ranging from 19.5mm - 132mm and accepts either 3.5mm cortex or pelvic screws. In addition the plates are manufactured from Stainless Steel and Commercially Pure Titanium and provided STERILE and NON STERILE.

1.5. Intended Use

The DePuy Synthes 3.5 mm Spring Plate is intended for pelvic and acetabular reconstructive surgery and fracture fixation 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 3.5mm Spring 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 3.5mm Spring 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 3.5 mm LCP Hook Plate – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K082072 Synthes (USA) 3.5mm LCP Hook Plate

1.4. Device Description

The DePuy Synthes 3.5 mm LCP Hook Plate is a low-profile, precontoured bone fixation plate intended for the treatment of fractures, osteotomies, and non-unions in small bones. The plates feature a preformed dual hook on one end and are available in stainless steel and titanium.

1.5. Intended Use

The DePuy Synthes 3.5 mm LCP Hook Plate is indicated for fractures, osteotomies and non-unions of small bones including the ulna, radius, tibia and fibula, particularly in osteopenic bone.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for DePuy Synthes 3.5 mm LCP 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 3.5 mm LCP 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 3.5 mm LCP Periarticular Proximal Humerus Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K082625 Synthes (USA) 3.5 mm LCP Periarticular Proximal Humerus Plates

1.4. Device Description

The DePuy Synthes 3.5 mm LCP Periarticular Proximal Humerus Plates are low-profile, pre-contoured bone fixation plates intended for the treatment of fractures of the humerus. The plates are offered sterile and non-sterile and are available in stainless steel and titanium.

1.5. Intended Use

The DePuy Synthes 3.5 mm LCP Periarticular Proximal Humerus Plates are indicated for fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for DePuy Synthes 3.5 mm LCP Periarticular Proximal Humerus 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 3.5 mm LCP Periarticular Proximal Humerus 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 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K082807 Synthes 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications

1.4. Device Description

The DePuy Synthes 3.5 mm and 4.5 mm LCP Plates with Expanded Indications consist on.5 mm LCP plates, 4.5 rom 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.

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1.5. Intended Use

The DePuy Synthes 3.5 mm Locking Compression Plate (LCP) System:

The DePuy Synthes 3.5 mm LCP is indicated for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, 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 (LCP) System:

The DePuy Synthes 4.5 mm LCP is indicated for fixation of various 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 fixation 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 DePuy Synthes 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications. 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 and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications 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 3.5mm Locking Attachment Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K083573 Synthes (USA) 3.5mm Locking Attachment Plates

1.4. Device Description

The DePuy Synthes 3.5mm Locking Attachment Plates are low-profile, pre-contoured plates which are intended to be used with existing Synthes LCP plates to stabilize fractures. The plates are available in stainless steel and titanium.

1.5. Indications for Use

The DePuy Synthes 3.5mm Locking Attachment Plate is intended for use with DePuy Synthes LCP plates to augment the stabilization of fractures, including periprosthetic fractures and fractures in the presence of intramedullary implants, in the femur, tibia and humerus, particularly in osteopenic bone.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for DePuy Synthes 3.5mm Locking Attachment 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 3.5mm Locking Attachment 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 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K092609 Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP)

1.4. Device Description

The DePuy Synthes Curved Narrow and Broad LCP Plates are available in stainless steel and titanium, and consist of limited-contact profile plates in 3.5 mm and 4.5mm narrow and broad sizes. The plates feature Dynamic Compression Plate (DCP) holes combined with locking screw holes. The 3.5mm plates accept 3.5mm cortex and locking screws and 4.0 mm cancellous screws, and the 4.5mm plates accept 4.5 mm cortex screws, 4.0mm and 5.0mm locking screws, 4.5 mm cannulated screws, 5.0 mm periprosthetic screws, and 6.5 mm cancellous screws.

1.5. Indications for Use

The DePuy Synthes 3.5 mm Curved Narrow and Broad LCP Plates are intended for fixation of fractures, osteotomies and non-unions of clavicle, scapula, olecranon, humerus, radius, pelvis, distal tibia and fibula, particularly in osteopenic bone for adult patients.

The DePuy Synthes 4.5 mm Curved Narrow and Broad LCP Plates are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of periprosthetic fractures, osteopenic bone, and non-unions or malunions in adult patients.

The DePuy Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad LCP Plates are also indicated for fracture fixation 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 DePuy Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP). 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 and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) 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 / 3.5 mm VA-LCP Anterior Clavicle 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

K101536 2.7 mm / 3.5 mm VA-LCP Anterior Clavicle Plate System

1.4. Device Description

The DePuy Synthes 2.7 mm / 3.5 mm VA-LCP Anterior Clavicle Plate System consists of plates of various lengths and variable angle screws that provide the flexibility to lock screws in trajectories that can diverge from the central axis of the plate hole.

The system features medial and lateral plates that are pre-contoured to match the anatomy of the clavicle and a limited contact, low profile design. The plate with lateral extension features Variable Angle (VA) Locking holes and Dynamic Compression Plate (DCP) holes. The medial plate features Dynamic Compression Plate (DCP) holes combined with VA locking screw holes.

1.5. Indications for Use

The DePuy Synthes 2.7 mm / 3.5 mm VA-LCP Anterior Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for DePuy Synthes 2.7 mm / 3.5 mm VA-LCP Anterior Clavicle 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 2.7 mm / 3.5 mm VA-LCP Anterior Clavicle 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 3.5 mm LCP Clavicle Plate System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K111540 Synthes 3.5 mm LCP Clavicle Plate System

1.4. Device Description

The DePuy Synthes 3.5 mm LCP Clavicle Plate System consists of metallic plates and screws that offer screw to plate locking designed for various fracture modes of the clavicle.

1.5. Indications for Use

The DePuy Synthes 3.5 mm LCP Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for DePuy Synthes 3.5 mm LCP Clavicle 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 LCP Clavicle 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 Variable Angle LCP Elbow System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K120070 Synthes Variable Angle LCP Elbow System

1.4. Device Description

The DePuy Synthes Variable Angle LCP Elbow System contains plates intended to treat fractures of the distal humerus and proximal ulna. A variety of plate configurations are included in the system to allow for fixation of multiple fracture patterns. Specifically, the system includes several plate configurations for fixation of the distal humerus which are intended to be used in a two-plate construct where plates are positioned medially and laterally. Additionally, the system includes plates for fixation of the olecranon and proximal ulna. In its entirety, the following plate types are included in the system:

- Medial Distal Humerus Plate
- Lateral Distal Humerus Plate
- Olecranon Plate
- Proximal Olecranon Plate

- Extra-articular Proximal Ulna Plate

The system accepts existing conical and locking screws as well as new metaphyseal screws, and allows for both dynamic compression and locking through Combi holes. The plates are universally designed for both left and right use and will be offered in both stainless steel and titanium.

1.5. Indications for Use

The DePuy Synthes Variable Angle LCP Elbow System is intended for fixation of fractures of the distal humerus, olecranon and ulna 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. Specifically,

- Distal humerus plates are indicated for intra-articular fractures, commninuted supracondylar fractures, osteotomies, malunions and non-unions of the distal humerus.

- Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for DePuy Synthes Variable Angle LCP Elbow 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 LCP Elbow 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.

DePuy Synthes People inspired™
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510(k) Summary

Date Prepared: October 31, 2018

1.1 Submitter

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1.2. Device

Name of Device: DePuy Synthes Variable Angle LCP Elbow System (Medial and Posterolateral Distal Humerus Plates) – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS, HWC

1.3. Predicate Device

K120717 Synthes Variable Angle LCP Elbow System (Medial and Posterolateral Distal Humerus Plates)

1.4. Device Description

The DePuy Synthes Variable Angle LCP Elbow System contains posterolateral and medial plates intended to treat fractures of the distal humerus. The plates are used together in a two-plate, 90° construct and accept existing screws. New 2.7mm Metaphyseal Screws are also compatible with the System.

1.5. Indications for Use

The DePuy Synthes Variable Angle LCP Elbow System is intended for fixation of fractures of the distal humerus, olecranon and ulna 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. Specifically,

- Distal humerus plates are indicated for intra-articular fractures, comminuted supracondylar fractures, osteotomies, malunions and non-unions of the distal humerus.

- Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for DePuy Synthes Variable Angle LCP Elbow System (Medial and Posterolateral Distal Humerus 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 Variable Angle LCP Elbow System (Medial and Posterolateral Distal Humerus 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.

510(k) Summary

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1.2. Device

Name of Device: DePuy Synthes TOMOFIX Osteotomy System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K141796 DePuy Synthes TOMOFIX Osteotomy System

1.4. Device Description

The DePuy Synthes TOMOFIX Osteotomy System consists of five different titanium plate families with locking and combination locking/compression holes. This system features plates designed to provide stable fixation of osteotomies of the distal femur and proximal tibia.

The DePuy Synthes TOMOFIX Medial Distal Femur Plates are part of the DePuy Synthes TOMOFIX Osteotomy System used for closed wedge femoral osteotomies. The subject plates are anatomically contoured to fit the medial distal femur, are available in right and left versions, as well as sterile and non-sterile.

1.5. Indications for Use

The DePuy Synthes TOMOFIX Osteotomy System is intended for osteotomies, treatment of bone and joint deformities, fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur and proximal tibia.

Specifically,

- The TOMOFIX Medial Proximal Tibia Plates are indicated for open- and closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the medial proximal tibia

- The TOMOFIX Lateral Proximal Tibia Plates are indicated for open- and closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the lateral proximal tibia

- The TOMOFIX Lateral Distal Femur Plates are indicated for open- and closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the lateral distal femur

- The TOMOFIX Medial Distal Femur Plates are indicated for closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the medial distal femur

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes TOMOFIX 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 TOMOFIX 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 2.4/2.7mm VA LCP Two-Column Volar Distal Radius Plate, Extra-Long – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K163046 DePuy Synthes 2.4/2.7mm VA LCP Two-Column Volar Distal Radius Plate, Extra-Long

1.4. Device Description

The DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long will be available in stainless steel and titanium. The head of the plate will remain the same as the existing 2.4mm VA-LCP Two-Column Volar Distal Radius Plate (K102694) and will therefore allow the use of the existing guide block for these plates. The DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long will come in 3 different lengths (7 shaft holes, 10 shaft holes and 13 shaft holes). To accommodate different patient anatomy, the plate with 7 shaft holes will be available with three different plate head widths (Standard, Narrow and Wide). The 10 shaft hole and the 13 shaft hole plate will only be released with the Standard plate head width and additionally they feature

a curvature in the shaft. All plates will feature left- and right-specific designs and will be offered in sterile packed only.

The DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plates, Extra-Long are designed to accept existing 2.4mm Variable Angle Locking Screws, 2.4mm Cortex Screws, 2.4mm Locking Screws, 1.8mm VA Buttress Pins and 1.8mm Locking Buttress Pins in the plate head holes. In the plate shaft, existing 2.4mm Cortex Screws, 2.7mm Cortex Screws, 2.4mm Variable Angle Locking Screws, 2.7mm Variable Angle Locking Screws, 2.4mm Locking Screws, and 2.7mm Locking Screws can be inserted.

1.5. Intended Use

The DePuy Synthes 2.4/2.7 mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long is intended for intra- and extra-articular fractures, osteotomies, nonunions and malunions of the distal radius, with or without extension into the radial diaphysis in adults and adolescents (12-21) where the growth plates have fused or will not be crossed, and the following adolescent distal radius fractures:

- Intra-articular fractures exiting the epiphysis
- Intra-articular fractures exiting the metaphysis
- Physeal crush injuries
- 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 DePuy Synthes 2.4/2.7mm VA LCP Two-Column Volar Distal Radius Plate, Extra-Long. 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 2.4/2.7mm VA LCP Two-Column Volar Distal Radius Plate, Extra-Long 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.