Synthes (USA) Products LLC/DePuy Orthopaedics Inc
Suchitra Basu
Global Strategy Manager, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

June 21, 2018

Re: K172975
Trade/Device Name: DePuy Synthes (USA) 5.0mm / 7.3mm Crimp Positioning Pins – MR Conditional, DePuy Synthes Variable Angle Positioning Pins – MR Conditional, DePuy Synthes Wire Mount – MR Conditional, DePuy Synthes Cerclage Positioning Pin – MR Conditional
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: May 11, 2018
Received: May 14, 2018

Dear Suchitra Basu:

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.

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,

Mark N. Melkerson -S

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

Enclosure

DePuy Synthes

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)*
K172975

Device Name
DePuy Synthes (USA) 5.0mm / 7.3mm Crimp Positioning Pins – MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes 5.0mm and 7.3mm Crimp Positioning Pins are intended for use with multifilament cable to augment fracture stabilization with plates used in long bone fixation when the use of screws is contraindicated, as in the presence of intramedullary implants.

The 5.0mm Crimp Positioning Pins are designed for use in the 5.0mm locking or 4.5mm LCP holes of Synthes plates. The 7.3mm Crimp Positioning Pins are designed for use in the 7.3mm locking holes of Synthes plates.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DePuy Synthes

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)*
K172975

Device Name
DePuy Synthes Variable Angle Positioning Pins – 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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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)*
K172975

Device Name
DePuy Synthes Wire Mount - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Wire Mount is intended for use with cerclage wire to augment fracture stabilization with plates used in long bone fixation when the use of screws is contraindicated, as in the presence of intramedullary implants.

The Wire Mount is designed for use in dynamic compression screw holes that accept a 4.5 mm bone screw. The Wire Mount (and cerclage wire) can be used with a variety of plates that include, but are not limited to the following: Dynamic Hip Screw (DHS) Plates, Dynamic Condylar Screw (DCS) Plates, Condylar Buttress Plates, Cobra Head Plates, Hook Plates, 4.5 mm Narrow and Broad Dynamic Compression Plates (DCP), 90° Child and Adolescent Osteotomy Plates, 110-130° Adult Osteotomy Plates, and 95° Condylar and 130° Angle Blade Plates (both including small stature plates).

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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DePuy Synthes

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)*
K172975

Device Name
DePuy Synthes Cerclage Positioning Pin- MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Cerclage Positioning Pins are intended for use with cerclage monofilament wire and multifilament cable to augment fracture stabilization with plates used in long bone fixation when the use of screws is contraindicated, as in the presence of intramedullary implants.

Cerclage Positioning Pins are designed for use with plates having locking compression or dynamic compression screw holes that accept a 3.5 mm or 4.5 mm bone screws. The Cerclage Positioning Pin (and cerclage wire or cable) can be used with a variety of Synthes plates.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DePuy Synthes

510(K) Summary for K081205:

Date Prepared: June 20, 2018

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes (USA) *5.0mm* / 7.3mm Crimp Positioning Pins – MR Conditional
Classification Name(s): Bone Fixation Cerclage
Common or Usual Name(s): crimp, pin, Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II; 888.3010
Product Code(s): JDQ

1.3. Predicate Device

Synthes 5.0mm/7.3mm (USA) Crimp Positioning Pins (K081205)

1.3.1 Reference Device

DePuy Synthes Trauma Orthopedic Implant Portfolio – MR Conditional (K160553)

1.4. Device Description

The DePuy Synthes 5.0 mm and 7.3 mm Crimp Positioning Pins are designed to fit into the screw holes of existing DePuy Synthes fixation plates for the purpose of providing a guide for Cerclage cable positioning as well as a crimping point for Cerclage cable tension fixation. The Crimp Positioning pins are available in versions composed of implant quality stainless steel and titanium.

DePuy Synthes

1.5. Indications for Use

The DePuy Synthes 5.0 mm and 7.3 mm Crimp Positioning Pins are intended for use with multifilament cable to augment fracture stabilization with plates used in long bone fixation when the use of screws is contraindicated, as in the presence of intramedullary implants.

The 5.0 mm Crimp Positioning Pins are designed for use in the 5.0 mm locking or 4.5 mm LCP holes of Synthes plates. The 7.3 mm Crimp Positioning Pins are designed for use in the 7.3 mm locking holes of Synthes Plates.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 5.0 mm and 7.3 mm Crimp Positioning Pins. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 5.0 mm and 7.3 mm Crimp Positioning Pins 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

510(k) Summary for K162124:

Date Prepared: June 20, 2018

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Variable Angle Positioning Pins – MR Conditional
Classification Name(s): Cerclage, Fixation
Common or Usual Name(s): pin, Smooth or thread metallic bone fixation fastener
Regulatory Class: Class II; 888.3010
Product Code(s): JDQ

1.3. Predicate Device

Synthes Variable Angle Positioning Pins (K162124)

1.3.1 Reference Device

DePuy Synthes Trauma Orthopedic Implant Portfolio – MR Conditional (K160553)

1.4. Device Description

The VA 5.0 Positioning Pins are designed for use with Variable Angle LCP plate implants featuring variable angle locking holes that accept 5.0mm variable angle bone screws. Positioning or cerclage pins are intended for use with cerclage monofilament wire or 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.

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 Variable Angle Positioning Pins. 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 Positioning Pins 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

510(k) Summary for K953777:

Date Prepared: June 20, 2018

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Wire Mount – MR Conditional
Classification Name(s): Cerclage, Fixation
Common or Usual Name(s): Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II; 888.3010
Product Code(s): JDQ

1.3. Predicate Device

Synthes Wire Mount (K953777)

1.3.1 Reference Device

DePuy Synthes Trauma Orthopedic Implant Portfolio – MR Conditional (K160553)

1.4. Device Description

The Wire Mount is intended for use with cerclage wire to augment fracture stabilization with plates when use of screws is contraindicated, as in the presence of intramedullary implants. The design is a "T" post with a hole perpendicular to the post axis, and a small triangular ridge on the bottom. Placing the post through the dynamic compression screw hole, inserting from the bone side of the plate, creates a stable structure for cerclage wire fixation. The cerclage wire is passed around the bone, through the wire mount hole above the outer surface of the plate, and then twisted with the opposite wire end.

1.5. Indications for Use

The DePuy Synthes Wire Mount is intended for use with cerclage wire to augment fracture

stabilization with plates used in long bone fixation when the use of screws is contraindicated, as in the presence of intramedullary implants.

The Wire Mount is designed for use in dynamic compression screw holes that accept a 4.5 mm bone screw. The Wire Mount (and cerclage wire) can be used with a variety of plates that include, but are not limited to the following: Dynamic Hip Screw (DHS) Plates, Dynamic Condylar Screw (DCS) Plates, Condylar Buttress Plates, Cobra Head Plates, Hook Plates, 4.5 mm Narrow and Broad Dynamic Compression Plates (DCP), 90° Child and Adolescent Osteotomy Plates, 110-130° Adult Osteotomy Plates, and 95° Condylar and 130° Angle Blade Plates (both including small stature plates).

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Wire Mount. The intended use and technological characteristics of the devices remain unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Wire Mount construct 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

510(k) Summary for K992891:

Date Prepared: June 20, 2018

1.1. Submitter

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1.2. Device

Name of Device: DePuy Synthes Cerclage Positioning Pin- MR Conditional
Classification Name(s): Cerclage, Fixation
Common or Usual Name(s): Smooth or thread metallic bone fixation fastener
Regulatory Class: Class II; 888.3010
Product Code(s): JDQ

1.3. Predicate Device

Synthes Cerclage Positioning Pin (K992891)

1.3.1 Reference Device

DePuy Synthes Trauma Orthopedic Implant Portfolio – MR Conditional (K160553)

1.4. Device Description

The design of the cerclage positioning pin is an oval body with a hole running perpendicular to the long axis (for use in compression holes), and has a stud protruding from the bottom. By placing the post through the top of the dynamic compression screw hole into a pre-drilled hole in cortical bone a stable structure is created for cerclage wire or cable fixation. The wire or cable is passed around the bone, through the Cerclage Positioning Pin hole above the outer plate surface, and then the wire is twisted or cable is crimped for final securement.

1.5. Indications for Use

DePuy Synthes

The DePuy Synthes Cerclage Positioning Pins are intended for use with cerclage monofilament wire and multifilament cable to augment fracture stabilization with plates used in long bone fixation when the use of screws is contraindicated, as in the presence of intramedullary implants.

Cerclage Positioning Pins are designed for use with plates having locking compression or dynamic compression screw holes that accept a 3.5 mm or 4.5 mm bone screw. The Cerclage Positioning Pin (and cerclage wire or cable) can be used with a variety of Synthes plates.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the Synthes Cerclage Positioning Pin. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the Synthes Cerclage Positioning Pin construct 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.