March 13, 2019

Synthes (USA) Products LLC
Rebecca Reiter
Regulatory Affairs Project Leader
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K183113
Trade/Device Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: MQN, DZL, NEI, OAT, DZK
Dated: February 14, 2019
Received: February 15, 2019

Dear Rebecca Reiter:

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,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes IMF Screws (originally cleared per K010527)

The DePuy Synthes IMF Screws are intended to provide indirect stabilization of the maxilla and mandible following maxillofacial and mandibular trauma or reconstruction.

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Titanium Multi-Vector Distractor (originally cleared per K010690)

The DePuy Synthes Titanium Multi-Vector Distractor is intended for use in mandibular bone lengthening for conditions such as mandibular hypoplasia or post-traumatic defects such as tumor resections, severe trauma, bone grafting defects, severe open mandible fractures where gradual distraction is required. Where bone loss is a result of the condition, bone transport can be performed as an alternative to free flaps or bone grafts.

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Low Profile Neuro System - 3 mm Screws (originally cleared via K031807)

The DePuy Synthes Low Profile Neuro System - 3 mm Screws is intended for use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes External Midface Distractor (originally cleared via K040083)

The DePuy Synthes External Midface Distractor is intended for use in maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy and/or the midface utilizing a LeFort II or III osteotomy in adult and pediatric populations where gradual bone distraction is required.

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes 1.0/1.2 mm Craniofacial Screws (originally cleared per K041887)

The DePuy Synthes 1.0/1.2 mm Craniofacial Screws are intended for use as follows:

General Indications:
• Maxillofacial surgery

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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K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Alveolar Distractor (originally cleared per K043555)

The DePuy Synthes Alveolar Distractor is intended for vertical bone lengthening of the alveolar ridge in the mandible and the maxilla where gradual bone distraction is required, including deficiency in bone height as a result of trauma, resorption after dental extraction, periodontal disease, tumor resection, and congenital deformity.

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Craniomaxillofacial Distraction System (CMF Distraction System) (originally cleared per K060138)

The DePuy Synthes Craniomaxillofacial Distraction System (CMF Distraction System) is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. The DePuy Synthes CMF Distraction System is intended for single use only.

The DePuy Synthes Pediatric CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required in children under the age of 12 months. The DePuy Synthes Pediatric CMF Distraction System is intended for single use only.

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)*
K183133

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Condylar Head Add-On System (originally cleared per K063181)

The DePuy Synthes Condylar Head Add-On System is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Curvilinear Distraction System (originally cleared per K080153)

The DePuy Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. This system is intended for use in either adults or pediatric patients over 1 year old. The DePuy Synthes Curvilinear Distraction System is intended for single use only.

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
Modification to DePuy Synthes Condylar Head Add-On System (originally cleared per K081747)

The DePuy Synthes Condylar Head Add-On System Intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Orthodontic Bone Anchor (OBA) System (originally cleared per K093299)

The DePuy Synthes Orthodontic Bone Anchor (OBA) System screw anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adolescents greater than age 12 and adults.

The DePuy Synthes Orthodontic Bone Anchor (OBA) System plate anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adults.

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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K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Curvilinear Distraction System (originally cleared per K121502)

The DePuy Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device. The DePuy Synthes Curvilinear Distraction System is indicated for correction of congenital deficiencies or posttraumatic defects of the mandibular body and ramus where gradual bone distraction is required.

The 2.0 mm Curvilinear Distractor is intended for use in adult and pediatric patients more than 1 year old.

The 1.3 mm Curvilinear Distractor is intended for use in pediatric patients 4 years of age and younger.

The DePuy Synthes Curvilinear Distraction System is intended for single use only.

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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K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Mandible Distractor (originally cleared per K962272)

The DePuy Synthes Mandible Distractor is intended to be used in the mandible for conditions such as mandibular deficiency or post-traumatic effects of the mandible, where gradual bone distraction is required.

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

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

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Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes SMF Stainless Steel Bone Screws (originally cleared via K964261)

The DePuy Synthes SMF Stainless Steel Bone Screws are intended for maxillofacial and mandibular trauma and reconstruction. The longer screw lengths (24-38mm) are specifically intended for symphysial fractures, parasymphyseal fractures, and angle fractures where the lag screw technique is being followed. The lag screw technique involves overdrilling the near cortex, thus the screw glides through the near cortical and cancellous bone and purchases only into the far cancellous and cortical 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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Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws (originally cleared per K980199)

The DePuy Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws are generally intended for a variety of pan facial indications. Specifically, it is intended for selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Single Vector Distractor with Detachable Feet (originally cleared per K981075)

The DePuy Synthes Single Vector Distractor with Detachable Feet is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or post-traumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating fonns of clefts of the lip and palate, and congenital mandibular hypoplasia, such as Hemifacial Microsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome.

The DePuy Synthes Single Vector Distractor with Detachable Feet is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes External Multi Vector Mandible Distractor (MVMD) (originally cleared via K981362)

The DePuy Synthes External Multi Vector Mandible Distractor (MVMD) is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or posttraumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating any form of congenital mandibular hypoplasia, such as Hemifacial Micorsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome.

The DePuy Synthes External MVMD is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Locking Reconstruction Plate (LRP) with Condylar Head (originally cleared per K990637)

The DePuy Synthes Locking Reconstruction Plate with Condylar Head is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

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)*
K183113

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Cerclage Wires (originally Pre-Amendment)

The DePuy Synthes Cerclage Wires are indicated for use in the jaws in adults and children to directly wire bony segments together, for the fixation of arch bars or splints to the teeth, for stabilization of bony segments, or for wiring the teeth together maxillomandibular fixation).

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510(k) Summary

Date Prepared: March 7, 2019

1.1. Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes IMF Screws

Classification Name(s): Screw, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZL

1.3. Predicate Device

K010527 Synthes IMF Screws

1.4. Device Description

This document is regarding the DePuy Synthes IMF Screws, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes IMF Screws are designed with cross-axial through holes and a circumferential relief groove to accommodate wire or elastic bands. The IMF Screws are self-drilling, 2.0 mm in diameter, and available in thread lengths of 6mm to 12mm. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5. Indications for Use

The DePuy Synthes IMF Screws are intended to provide indirect stabilization of the maxilla and mandible following maxillofacial and mandibular trauma or reconstruction.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes IMF Screws. Changes in the Indications for Use Statement are to remove language not specific to maxillofacial surgeries, as these (e.g., craniofacial) indications are not reviewed by the Dental Review Panel. The technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K010527
The DePuy Synthes IMF Screws are intended to provide indirect stabilization of the maxilla and mandible following maxillofacial and mandibular trauma or reconstruction.	To provide indirect stabilization of the maxilla and mandible following craniofacial and mandibular trauma or reconstruction.

1.7. Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes IMF Screws in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a and DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1. Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Titanium Multi-Vector Distractor

Classification Name(s): Screw, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZL

1.3. Predicate Device

K010690 Synthes Titanium Multi-Vector Distractor

1.4. Device Description

This document is regarding the DePuy Synthes Titanium Multi-Vector Distractor, which are a supset of the DePuy Synthes Maxillofacial Portfolio-MR Conditional. The DePuy Synthes Titanium Multi-Vector Distractor (MVD) is a bone lengthening and distraction device that functions by gradually activating the device in a linear, angular, and/or transverse fashion. Bone stabilization may also be accomplished with this device after distraction. The device is comprised of interchangeable distraction arms, various pin clamps, socket and hex head screws, rods, and activation nuts. All MVD pin clamps accommodate 2.0mm k-wires. The

devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5. Indications for Use

The DePuy Synthes Titanium Multi-Vector Distractor is intended for use in mandibular bone lengthening for conditions such as mandibular hypoplasia or post-traumatic defects such as tumor resections, severe trauma, bone grafting defects, severe open mandible fractures where gradual distraction is required. Where bone loss is a result of the condition, bone transport can be performed as an alternative to free flaps or bone grafts.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Titanium Multi-Vector Distractor. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K010690
The DePuy Synthes Titanium Multi-Vector Distractor is intended for use in mandibular bone lengthening for conditions such as mandibular hypoplasia or post-traumatic defects such as tumor resections, severe trauma, bone grafting defects, severe open mandible fractures where gradual distraction is required. Where bone loss is a result of the condition, bone transport can be performed as an alternative to free flaps or bone grafts.	For use in mandibular bone lengthening for conditions such as mandibular hypoplasia or post-traumatic defects such as tumor resections, severe trauma, bone grafting defects, severe open mandible fractures where gradual distraction is required. Where bone loss is a result of the condition, bone transport can be performed as an alternative to free flaps or bone grafts.

1.7. Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Titanium Multi-Vector Distractor 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1. Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Low Profile Neuro System - 3 mm Screws

Classification Name(s): Screw, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZL

1.3. Predicate Device

K031807 Synthes Low Profile Neuro System - 3 mm Screws

1.4. Device Description

This document is regarding the DePuy Synthes Low Profile Neuro System - 3 mm Screws, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. Synthes ø1.6 mm Low Profile Neuro System self-drilling, self·tapping, and ø1.9 mm emergency self-tapping screws in 3 mm lengths are to be added to the system. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5. Indications for Use

The DePuy Synthes Low Profile Neuro System - 3 mm Screws is intended for use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Low Profile Neuro System - 3 mm Screws. Changes in the Indications for Use Statement are to remove language not specific to maxillofacial surgeries, as these (e.g., craniofacial) indications are not reviewed by the Dental Review Panel. The technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K031807
The DePuy Synthes Low Profile Neuro System - 3 mm Screws is intended for use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	Synthes Low Profile Neuro System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

1.7. Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Low Profile Neuro System - 3 mm Screws in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a and DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1. Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes External Midface Distractor

Classification Name(s): External Mandibular Fixator And/Or Distractor

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3. Predicate Device

K040083 Synthes External Midface Distractor

1.4. Device Description

This document is regarding the DePuy Synthes External Midface Distractor, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes External Midface Distractor is an external distraction osteogenesis device that attaches to the midface and is used to gradually lengthen the midface at the LeFort I, II, and III levels. The device consists of an external headframe, a central adjustment mechanism, a veridical central rod, horizontal crosspieces containing distraction screws, and separate footplates assemblies that attach to the zygoma and maxilla. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5. Indications for Use

The DePuy Synthes External Midface Distractor is intended for use in maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy and/or the midface utilizing a LeFort II or III osteotomy in adult and pediatric populations where gradual bone distraction is required.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes External Midface Distractor. Changes in the Indications for Use Statement are to remove language not specific to maxillofacial surgeries, as these (e.g., craniofacial) indications are not reviewed by the Dental Review Panel. The technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K040083
The DePuy Synthes External Midface Distractor is intended for use in maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy and/ or the midface utilizing a LeFort II or III osteotomy in adult and pediatric populations where gradual bone distraction is required.	The Synthes External Midface Distractor is intended for use in craniofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy, the midface utilizing a LeFort II or III osteotomy, and / or the cranium utilizing a monobloc osteotomy in adult and pediatric populations where gradual bone distraction is required.

1.7. Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes External Midface Distractor 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes 1.0/1.2 mm Craniofacial Screws

Classification Name(s): Screw, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZL

1.3 Predicate Device

K041887 Synthes 1.0/1.2 mm Craniofacial Screws

1.4 Device Description

This document is regarding the DePuy Synthes 1.0/1.2 mm Craniofacial Screws, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes 1.0/1.2 mm Craniofacial Screws are either self-drilling or self tapping, have a flat head profile with rounded edges with a cruciform recess, and are available in various lengths. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes 1.0/1.2 mm Craniofacial Screws are intended for use as follows:

General Indications:

- Maxillofacial surgery

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 1.0/1.2 mm Craniofacial Screws. Changes in the Indications for Use Statement are to remove language not specific to maxillofacial surgeries, as these (e.g., craniofacial) indications are not reviewed by the Dental Review Panel. The technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K041887
The DePuy Synthes 1.0/1.2 mm Craniofacial Screws are intended for use as follows: General Indications: • Maxillofacial surgery	The Synthes 1.0/1.2 mm Craniofacial Screws are intended for use as follows: Specific Indications: • Nasoethmoidal fractures • Infraorbital area fractures • Frontal sinus wall fractures • Infant craniofacial surgery General Indications: • Maxillofacial surgery

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 1.0/1.2 mm Craniofacial Screws in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a and DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1. Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Alveolar Distractor

Classification Name(s): External Mandibular Fixator And/Or Distractor

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3. Predicate Device

K043555 Synthes Alveolar Distractor

1.4. Device Description

This document is regarding the DePuy Synthes Alveolar Distractor, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Alveolar Distractor is an extraosseous distraction device consisting of a distractor body, a transport plate, a base plate, and a vector control mechanism. It is intended to be placed submucosally, with the base plate fastened to the stationary segment of the mandible or maxilla and the transport plate fastened to the mobile bone segment. The plates are fixed to the bone using 1.5 mm cortex screws. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5. Indications for Use

The DePuy Synthes Alveolar Distractor is intended for vertical bone lengthening of the alveolar ridge in the mandible and the maxilla where gradual bone distraction is required, including deficiency in bone height as a result of trauma, resorption after dental extraction, periodontal disease, tumor resection, and congenital deformity.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Alveolar Distractor. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K043555
The DePuy Synthes Alveolar Distractor is intended for vertical bone lengthening of the alveolar ridge in the mandible and the maxilla where gradual bone distraction is required, including deficiency in bone height as a result of trauma, resorption after dental extraction, periodontal disease, tumor resection, and congenital deformity.	The Synthes Alveolar Distractor is intended for vertical bone lengthening of the alveolar ridge in the mandible and the maxilla where gradual bone distraction is required, including deficiency in bone height as a result of trauma, resorption after dental extraction, periodontal disease, tumor resection, and congenital deformity.

1.7. Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Alveolar Distractor 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1. Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Craniomaxillofacial Distraction System (CMF Distraction System)

Classification Name(s): External Mandibular Fixator And/Or Distractor

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3. Predicate Device

K060138 Synthes Craniomaxillofacial Distraction System (CMF Distraction System)

1.4. Device Description

This document is regarding the DePuy Synthes Craniomaxillofacial Distraction System (CMF Distraction System), which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Craniomaxillofacial Distraction System, which includes the Pediatric CMF Distraction System, is a modular family of internal distraction osteogenesis devices that are used to gradually lengthen the mandible body and ramus. Each device, when assembled, is comprised of a distractor body, two footplates, and a machine screw to secure

the assembly. The system also includes optional activation arms, which can be attached to the activation end of the device to move the point of activation to an area accessible by the activation instrument. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Craniomaxillofacial Distraction System (CMF Distraction System) is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. The DePuy Synthes CMF Distraction System is intended for single use only.

The DePuy Synthes Pediatric CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required in children under the age of 12 months. The DePuy Synthes Pediatric CMF Distraction System is intended for single use only.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Craniomaxillofacial Distraction System. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K060138
The DePuy Synthes Craniomaxillofacial Distraction System (CMF Distraction System) is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. The DePuy Synthes CMF Distraction System is intended for single use only. The DePuy Synthes Pediatric CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required in children under the age of 12 months. The DePuy Synthes Pediatric CMF Distraction System is intended for single use only.	The Synthes Craniomaxillofacial Distraction System (CMF Distraction System) is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. The Synthes CMF Distraction System is intended for single use only. The Synthes Pediatric CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required in children under the age of 12 months. The Synthes Pediatric CMF Distraction System is intended for single use only.

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Craniomaxillofacial Distraction 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Condylar Head Add-On System

Classification Name(s): Prosthesis, Condyle, Mandibular, Temporary

Regulatory Class: Class II; 872.4770

Product Code(s): NEI

1.3 Predicate Device

K063181 Synthes Condylar Head Add-On System

1.4 Device Description

This document is regarding the DePuy Synthes Condylar Head Add-On System, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Condylar Head Add-On System is an adjustable height system intended for use with DePuy Synthes' 2.4 mm Locking Reconstruction Plate (LRP) System. The system consists of an elliptical shaped condylar head, four different fixation plates which allow the surgeon to adjust the height of the condylar head, and two fixation screws for mounting the condylar head and fixation plate onto a 2.4 mm locking reconstruction plate. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Condylar Head Add-On System is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Condylar Head Add-On System. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K063181
The DePuy Synthes Condylar Head Add-On System is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).	The Synthes Condylar Head Add-On System is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Condylar Head Add-On 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Curvilinear Distraction System

Classification Name(s): External Mandibular Fixator And/Or Distractor

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3 Predicate Device

K080153 Synthes Curvilinear Distraction System

1.4 Device Description

This document is regarding the DePuy Synthes Curvilinear Distraction System, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Curvilinear Distraction System is an internal distraction osteogenesis device that gradually advances the mandible along a specific path of distraction. The system features various curved and straight distractors which are fixed to the mandible with bone screws. The distractors accept extension arms which move the point of activation to a location that is easily accessible with the activation instrument. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. This system is intended for use in either adults or pediatric patients over 1 year old. The DePuy Synthes Curvilinear Distraction System is intended for single use only.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Curvilinear Distraction System. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K080153
The DePuy Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. This system is intended for use in either adults or pediatric patients over 1 year old. The DePuy Synthes Curvilinear Distraction System is intended for single use only.	The Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus where gradual bone distraction is required. This system is intended for use in either adults or pediatric patients over 1 year old. The DePuy Synthes Curvilinear Distraction System is intended for single use only.

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Curvilinear Distraction 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: Modification to DePuy Synthes Condylar Head Add-On System

Classification Name(s): Prosthesis, Condyle, Mandibular, Temporary

Regulatory Class: Class II; 872.4770

Product Code(s): NEI

1.3 Predicate Device

K081747 Modification to Synthes Condylar Head Add-On System

1.4 Device Description

This document is regarding the DePuy Synthes Modification to Synthes Condylar Head Add-On System, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Condylar Head Add-On System is an adjustable height add-on system for use with the 2.4 mm Locking Reconstruction Plate System and MatrixMANDIBLE Plate System. It consists of a condylar head, 2 screws, and one of four (4) fixation plates, each with a different screw hole spacing that determines the height of the condylar head. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Condylar Head Add-On System Intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Condylar Head Add-On System. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K081747
The DePuy Synthes Condylar Head Add-On System Intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).	The Synthes Condylar Head Add-On System Intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Condylar Head Add-On 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Orthodontic Bone Anchor (OBA) System

Classification Name(s): Implant, Endosseous, Orthodontic

Regulatory Class: Class II; 872.3640

Product Code(s): OAT

1.3 Predicate Device

K093299 Synthes Orthodontic Bone Anchor (OBA) System

1.4 Device Description

This document is regarding the DePuy Synthes Orthodontic Bone Anchor (OBA) System, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Orthodontic Bone Anchor (OBA) System is intended to be implanted intraorally and used as an anchor for orthodontic procedures. The System includes screw anchors, plate anchors, instruments, and a module case for storage and sterilization.

Screw Anchors
The screw anchor portion of the system consists of 1.55 nun self-drilling and selftapping screw anchors which incorporate a non-treaded gingival collar beneath the screw head to protect the soft tissue. Once implanted, orthodontic appliances such as archwires, elastics, and springs can be attached to the head of the anchor. The screw anchors are manufactured from titanium alloy (Ti-6A1-7Nb).

Plate Anchors
The plate anchor portion of the system consists of T-shaped plate anchors which are attached to the bone via 1.55 mim cortex screws and 1.85 mma emergency screws. The plate anchors are offered in three designs (mesh, bracket, and domed)to allow attachment of orthodontic devices such as brackets, archwires, elastics, and springs. The plate anchors are manufactured from commercially pure titanium. The screws used to fix the plate anchors to the bone are manufactured from titanium alloy (Ti-6A-7Nb).

The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Orthodontic Bone Anchor (OBA) System screw anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adolescents greater than age 12 and adults.

The DePuy Synthes Orthodontic Bone Anchor (OBA) System plate anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adults.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Orthodontic Bone Anchor (OBA) System. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K093299
The DePuy Synthes Orthodontic Bone Anchor (OBA) System screw anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adolescents greater than age 12 and adults. The DePuy Synthes Orthodontic Bone Anchor (OBA) System plate anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adults.	The Synthes Orthodontic Bone Anchor (OBA) System screw anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adolescents greater than age 12 and adults. The Synthes Orthodontic Bone Anchor (OBA) System plate anchors are intended to be implanted intraorally and used as an anchor for orthodontic procedures in adults.

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Orthodontic Bone Anchor (OBA) 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Curvilinear Distraction System

Classification Name(s): External Mandibular Fixator And/Or Distractor

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3 Predicate Device

K121502 Synthes Curvilinear Distraction System

1.4 Device Description

This document is regarding the DePuy Synthes Curvilinear Distraction System, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Curvilinear Distraction System is a family of internal distraction osteogenesis devices that gradually advance the mandible along a specific trajectory of distraction. The system features various curved and straight distractors in two sizes; the 1.3mm Curvilinear Distractor and the 2.0mm Curvilinear Distractor. The distractors accept extension arms which move the point of activation to a location that is easily accessible with the activation instrument.

The DePuy Synthes Curvilinear Distraction devices are manufactured from, titanium alloy and chromium cobalt alloy. Devices are supplied non-sterile and must be sterilized prior to use. The distractor features a worm gear that is activated to move the distractor along a curved or straight track. The distractor consists of three main components:

- **Track**: The track has grooves in Imm intervals which may be placed in a straight line (for a straight distractor) or on a centerline radius (for a curved distractor). The track is manufactured with a crimp that serves as a functional stop to prevent the distractor from separating at the end of the track. The track is 35mm in length and can be cut to the desired length for each particular patient by the surgeon. After cutting, the track is crimped to re-establish the functional stop to prevent separation.
- **Worm gear activation assembly**: The worm activation assembly consists of the worm gear and a universal joint activation hex. The universal joint is capable of + or - 35 degree of angulation. The worm gear has a 1 mm pitch and rides along the grooves cut into the track. The worm gear activation assembly is inserted into the housing and the track with grooves is threaded through a slot in the side of the housing.
- **Housing**: The housing includes a tab that lays on the activation assembly to prevent the distractor from reversing due to micromotion.

The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device. The DePuy Synthes Curvilinear Distraction System is indicated for correction of congenital deficiencies or posttraumatic defects of the mandibular body and ramus where gradual bone distraction is required.

The 2.0 mm Curvilinear Distractor is intended for use in adult and pediatric patients more than 1 year old.

The 1.3 mm Curvilinear Distractor is intended for use in pediatric patients 4 years of age and younger.

The DePuy Synthes Curvilinear Distraction System is intended for single use only.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Curvilinear Distraction System. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K121502
The DePuy Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device. The DePuy Synthes Curvilinear Distraction System is indicated for correction of congenital deficiencies or posttraumatic defects of the mandibular body and ramus where gradual bone distraction is required. The 2.0 mm Curvilinear Distractor is intended for use in adult and pediatric patients more than 1 year old. The 1.3 mm Curvilinear Distractor is intended for use in pediatric patients 4 years of age and younger. The DePuy Synthes Curvilinear Distraction System is intended for single use only.	The Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device. The Synthes Curvilinear Distraction System is indicated for correction of congenital deficiencies or posttraumatic defects of the mandibular body and ramus where gradual bone distraction is required. The 2.0 mm Curvilinear Distractor is intended for use in adult and pediatric patients more than 1 year old. The 1.3 mm Curvilinear Distractor is intended for use in pediatric patients 4 years of age and younger. The Synthes Curvilinear Distraction System is intended for single use only.

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Curvilinear Distraction 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Mandible Distractor

Classification Name(s): External Mandibular Fixator And/Or Distractor

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3 Predicate Device

K962272 Synthes Mandible Distractor

1.4 Device Description

This document is regarding the DePuy Synthes Mandible Distractor, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Mandible Distractor is intended to be used in the mandible for conditions such as mandibular deficiency or post-traumatic effects of the mandible, where gradual bone distraction is required. The Mandible Distractor is a subcutaneous bone distractor. It features two telescoping components activated by a jack screw, fixed to the bone via subcutaneous plates and secured with 2.0 mrn or 2.4 mm bone screws. A hex driver is used to activate the required distraction. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Mandible Distractor is intended to be used in the mandible for conditions such as mandibular deficiency or post-traumatic effects of the mandible, where gradual bone distraction is required.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Mandible Distractor. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K962272
The DePuy Synthes Mandible Distractor is intended to be used in the mandible for conditions such as mandibular deficiency or post-traumatic effects of the mandible, where gradual bone distraction is required.	The Synthes Mandible Distractor is intended to be used in the mandible for conditions such as mandibular deficiency or post-traumatic effects of the mandible, where gradual bone distraction is required.

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Mandible Distractor 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes SMF Stainless Steel Bone Screws

Classification Name(s): Screw, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZL

1.3 Predicate Device

K964261 Synthes SMF Stainless Steel Bone Screws

1.4 Device Description

This document is regarding the DePuy Synthes SMF Stainless Steel Bone Screws, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. SMF Stainless Steel Bone Screws are intended for maxillofacial and mandibular trauma and reconstruction. The screws feature self-tapping tips and a cruciform drive recess. The screws are available in various lengths ranging from 4 to 38 mm. The longer screw lengths (24 - 38 mm) are specifically intended for symphyseal fractures, parasymphyseal fractures, and angle fractures where the lag screw technique is being followed. The lag screw technique involves over-drilling the near cortex, thus the screw glides through the near cortical and cancellous bone and purchases only

into the far cancellous and cortical bone. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes SMF Stainless Steel Bone Screws are intended for maxillofacial and mandibular trauma and reconstruction. The longer screw lengths (24-38mm) are specifically intended for symphysial fractures, parasymphyseal fractures, and angle fractures where the lag screw technique is being followed. The lag screw technique involves overdrilling the near cortex, thus the screw glides through the near cortical and cancellous bone and purchases only into the far cancellous and cortical bone.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes SMF Stainless Steel Bone Screws. Changes in the Indications for Use Statement are to remove language not specific to maxillofacial surgeries, as these (e.g., craniofacial) indications are not reviewed by the Dental Review Panel. The technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K964261
The DePuy Synthes SMF Stainless Steel Bone Screws are intended for maxillofacial and mandibular trauma and reconstruction. The longer screw lengths (24-38mm) are specifically intended for symphysial fractures, parasymphyseal fractures, and angle fractures where the lag screw technique is being followed. The lag screw technique involves overdrilling the near cortex, thus the screw glides through the near cortical and cancellous bone and purchases only into the far cancellous and cortical bone.	The Synthes SMF Stainless Steel Bone Screws are intended for craniofacial and mandibular trauma and reconstruction. The longer screw lengths (24-38mm) are specifically intended for symphysial fractures, parasymphyseal fractures, and angle fractures where the lag screw technique is being followed. The lag screw technique involves overdrilling the near cortex, thus the screw glides through the near cortical and cancellous bone and purchases only into the far cancellous and cortical bone.

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes SMF Stainless Steel Bone Screws in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a and DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws

Classification Name(s): Screw, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZL

1.3 Predicate Device

K980199 Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws

1.4 Device Description

This document is regarding the DePuy Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes 1.5 mm /2.0 mm Orthognathic Maxillary Plates are available in Mesh-, T-, L, and Z- plate configurations, and attach to bone via 1.5 mm and 2.0 mm self-tapping screws, and 2.0 mm and 2.4 mm emergency screws. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws are generally intended for a variety of pan facial indications. Specifically, it is intended for selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws. Changes in the Indications for Use Statement are to remove language not specific to maxillofacial surgeries, as these (e.g., craniofacial) indications are not reviewed by the Dental Review Panel. The technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K980199
The DePuy Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws are generally intended for a variety of pan facial indications. Specifically, it is intended for selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	The Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws are generally intended for a variety of pan facial indications. Specifically, it is intended for selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 1.5 mm/2.0 mm Orthognathic Maxillary Plates and Screws in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a and DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Single Vector Distractor with Detachable Feet

Classification Name(s): External Mandibular Fixator And/Or Distractor

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3 Predicate Device

K981075 Synthes Single Vector Distractor with Detachable Feet

1.4 Device Description

This document is regarding the DePuy Synthes External Mandibular Fixator And/Or Distractor, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Single Vector Distractor with Detachable Feet is a subcutaneous bone distractor activated by a drive component. It features two telescoping components activated by a jack screw, fixed to the bone with bone screws. Bone lengthening and distraction are achieved by gradually activating the device. Upon removal, the telescoping components and jack screw are

disengaged and removed, leaving the subcutaneous foot plates in the patient. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Single Vector Distractor with Detachable Feet is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or post-traumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating fonns of clefts of the lip and palate, and congenital mandibular hypoplasia, such as Hemifacial Microsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome.

The DePuy Synthes Single Vector Distractor with Detachable Feet is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of bone.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Single Vector Distractor with Detachable Feet. Changes in the Indications for Use Statement are to remove language not specific to maxillofacial surgeries, as these (e.g., craniofacial) indications are not reviewed by the Dental Review Panel. The technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K981075
The DePuy Synthes Single Vector Distractor with Detachable Feet is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or post-traumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating fonns of clefts of the lip and palate, and congenital mandibular hypoplasia, such as Hemifacial Microsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome. The DePuy Synthes Single Vector Distractor with Detachable Feet is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of bone.	The Synthes Single Vector Distractor with Detachable Feet is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or post-traumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating fonns of clefts of the lip and palate, and congenital mandibular hypoplasia, such as Hemifacial Microsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome. The Synthes Single Vector Distractor with Detachable Feet is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of bone. The Synthes Single Vector Distractor with Detachable Feet can be used for stabilization and advancement of the mid-face, in which a deficiency of mid-facial bone requires gradual bone distraction. Such deficiencies include, but are not limited to Plagiocephaly, Trigonocephaly, Scaphocephaly, and Brachycephaly.

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Single Vector Distractor with Detachable Feet 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1. Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes External Multi Vector Mandible Distractor (MVMD)

Classification Name(s): Screw, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZL

1.3. Predicate Device

K981362 Synthes External Multi Vector Mandible Distractor (MVMD)

1.4. Device Description

This document is regarding the DePuy Synthes External Multi Vector Mandible Distractor (MVMD), which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes External Multi Vector Mandible Distractor (MVMD) is a bone lengthening and distraction device which is achieved by gradually activating the device in a linear, angular, and/or transverse fashion. Bone stabilization may also be achieved with this device after distraction.

The DePuy Synthes External MVMD is comprised of two interchangeable distraction arms, pin clamps, universal clamps, rods, flat head screws, and activation nuts. The pin clamps can accept 2.0mm k-wires.

The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5. Indications for Use

The DePuy Synthes External Multi Vector Mandible Distractor (MVMD) is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or posttraumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating any form of congenital mandibular hypoplasia, such as Hemifacial Micorsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome.

The DePuy Synthes External MVMD is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of bone.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes External Multi Vector Mandible Distractor (MVMD). The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K981362
The DePuy Synthes External Multi Vector Mandible Distractor (MVMD) is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or posttraumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating any form of congenital mandibular hypoplasia, such as Hemifacial Micorsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome. The DePuy Synthes External MVMD is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of bone.	The Synthes External Multi Vector Mandible Distractor (MVMD) is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or posttraumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating any form of congenital mandibular hypoplasia, such as Hemifacial Micorsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome. The Synthes External MVMD is also ideal for treating hypoplasias of an acquired origin such as from post-traumatic growth disorders associated with injury to the temporomandibular joint, temporomandibular ankylosis, and segmental loss of bone.

1.7. Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes External Multi Vector Mandible Distractor (MVMD) 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: DePuy Synthes Locking Reconstruction Plate (LRP) with Condylar Head

Classification Name(s): Prosthesis, Condyle, Mandibular, Temporary

Regulatory Class: Class II; 872.4770

Product Code(s): NEI

1.3 Predicate Device

K990637 Synthes Locking Reconstruction Plate (LRP) with Condylar Head

1.4 Device Description

This document is regarding the DePuy Synthes Locking Reconstruction Plate (LRP) with Condylar Head, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Locking Reconstruction Plate (LRP) with Condylar Head is a one piece reconstruction plate with a solid condylar head. The plate features compression screw holes that are internally threaded to accept the 2.4 - 3.0mm locking screws or standard 2.4 mm self-tapping cortex screws and has notched sides and undersides to facilitate contouring. The plates are available in three sizes for right and left placement. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Locking Reconstruction Plate with Condylar Head is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Locking Reconstruction Plate (LRP) with Condylar Head. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. An indications for use comparison table is provided below.

K183113	K990637
The DePuy Synthes Locking Reconstruction Plate with Condylar Head is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).	The Synthes Locking Reconstruction Plate with Condylar Head is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Locking Reconstruction Plate (LRP) with Condylar Head 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 DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 7, 2019

1.1 Submitter

Primary Contact:
Rebecca Reiter
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-1268
Email: rreiter@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Email: ejacob10@its.jnj.com

1.2 Device

Trade Name: DePuy Synthes Maxillofacial Portfolio - MR Conditional

Name of Device: Cerclage Wires

Classification Name(s): Wire, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZK

1.3 Predicate/Reference Devices

Primary Predicate: K092530 SPRYTIE, MODELS ST001, ST002 AND ST003

Reference Device: Synthes Pre-Amendment Cerclage Wires

1.4 Device Description

This document is regarding the DePuy Synthes Cerclage Wires, which are a subset of the DePuy Synthes Maxillofacial Portfolio – MR Conditional. The DePuy Synthes Cerclage Wires are used to augment fracture stabilization with or without plates. The wire is available in a variety of diameters. The wires are pre-cut to a usable length or available in coils allowing the surgeon to cut the length to his patient's needs. The devices in scope of K183113 are being reviewed for MR Conditional labeling for maxillofacial indications.

1.5 Indications for Use

The DePuy Synthes Cerclage Wires are indicated for use in the jaws in adults and children to directly wire bony segments together, for the fixation of arch bars or splints to the teeth, for stabilization of bony segments, or for wiring the teeth together maxillomandibular fixation.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Cerclage Wires. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes. DePuy Synthes selected K092530 as the predicate device for the Pre-Amendment Cerclage Wires, as the indications for use are similar as well as the device's application. An indications for use comparison table is provided below.

K183113	K092530	Pre-Amendment
The DePuy Synthes Cerclage Wires are indicated for use in the jaws in adults and children to directly wire bony segments together, for the fixation of arch bars or splints to the teeth, for stabilization of bony segments, or for wiring the teeth together maxillomandibular fixation.	Sprytie wires are indicated for use in the jaws in adults and children to directly wire bony segments together, for the fixation of arch bars or splints to the teeth, for stabilization of bony segments, are for wiring the teeth together (maxillomandibular fixation).	This device is Pre-Amendment and does not have an indications for use statement.

1.7 Non-Clinical Testing Summary

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Cerclage Wires in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a and DUKE model), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

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.