December 30, 2019

Synthes (USA) Products LLC
Satapa Dhamankar
Regulatory Affairs Specialist II
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K192655
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: JEY
Dated: December 23, 2019
Received: December 26, 2019

Dear Satapa Dhamankar:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes MatrixWAVE MMF System (originally cleared per K141165)

The DePuy Synthes MatrixWAVE MMF System is indicated for the temporary treatment of mandibular and maxillary fractures and osteotomies in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes MatrixMANDIBLE Plate and Screw System (originally cleared per K121574)

The DePuy Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery:
- Trauma
- Reconstructive surgery
- Orthognathic surgery (surgical correction of dentofacial deformities)

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

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

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510(k) Number *(if known)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes MatrixMANDIBLE Plate and Screw System (originally cleared per K113567)

The DePuy Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery:
- Trauma
- Reconstructive surgery
- Orthognathic surgery (surgical correction of dentofacial deformities)

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

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

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510(k) Number *(if known)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Dentoalveolar Bone Fixation System (originally cleared per K102656)

The DePuy Synthes Dentoalveolar Bone Fixation System is intended for use in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in reconstruction of maxillary and/or mandibular areas, including the dentoalveolar ridge.

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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes MatrixMANDIBLE Subcondylar Plates (originally cleared per K091233)

The DePuy Synthes MatrixMANDIBLE Subcondylar Plates are intended for oral, maxillofacial surgery; trauma and reconstructive surgery, specifically for fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.

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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes MatrixMANDIBLE Preformed Reconstruction Plates (originally cleared per K091144)

The DePuy Synthes MatrixMANDIBLE Preformed Reconstruction Plates are intended for use in oral and maxillofacial surgery, trauma and reconstructive surgery. This includes primary mandibular reconstruction, comminuted fractures and temporary bridging pending delayed secondary reconstruction, including fractures of edentulous and/or atrophic mandibles, as well as unstable fractures.

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

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

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510(k) Number *(if known)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes MatrixORTHOGNATHIC Plating System (originally cleared per K083388)

The DePuy Synthes MatrixORTHOGNATHIC Plating System consists of a variety of plates that come in a variety of shapes and sizes to meet the anatomical needs of the patient. This system is designed for use with Synthes Matrix screws. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

The Synthes MatrixORTHOGNATHIC Plating System is intended for use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults.
Specific Indications for Use:
• Fractures of the midface and maxillofacial skeleton
• LeFort I osteotomies, sagittal split osteotomies and genioplasties
• Orthognathic surgery including reconstructive procedures

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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes MatrixMANDIBLE Plate and Screw System (originally cleared per K082335)

The DePuy Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

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

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

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510(k) Number *(if known)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Craniofacial Plate and Screw System (originally cleared per K080331)

The DePuy Synthes Craniofacial Plate and Screw System 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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes MatrixMANDIBLE Plate and Screw System (originally cleared per K063790)

The DePuy Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

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

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

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510(k) Number *(if known)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Craniofacial Plate and Screw System (originally cleared per K050608)

The DePuy Synthes Craniofacial Plate and Screw System 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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Neuro Plate and Screw System (originally cleared per K042365)

The DePuy Synthes Neuro Plate and Screw System 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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K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates (originally cleared per K033121)

The DePuy Synthes 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates are 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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Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Orbital Plates (originally cleared per K031761)

The DePuy Synthes Orbital Plates are 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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K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Low Profile Neuro System (originally cleared per K022012)

The DePuy Synthes Low Profile Neuro System 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)*

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DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Midface Distractor (Originally cleared per K022005)

The DePuy Synthes Midface Distractor is intended for use in adult and pediatric populations for the treatment of midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of the midfacial bones.

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

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

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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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Translating Maxillary Distractor (Originally cleared per K020505)

The DePuy Synthes Translating Maxillary 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 in adult and pediatric populations.

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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Midface Distractor (Originally cleared per K010499)

The DePuy Synthes Midface Distractor is intended for use in adult and pediatric populations for the treatment of midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of the midfacial bones.

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

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

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510(k) Number *(if known)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Maxillary Distractor (Originally cleared per K003393)

The DePuy Synthes Maxillary 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 in adult and pediatric populations.

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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Orbital Mesh Plates (Originally cleared per K001311)

The DePuy Synthes Orbital Mesh Plates for the Midfacial System are indicated 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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510(k) Number *(if known)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes 2.0 mm Locking Plate System (2.0 LPS) (originally cleared per K974555)

The DePuy Synthes 2.0 LPS is intended for oral, maxillofacial surgery: trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

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

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

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510(k) Number *(if known)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes 2.4 mm Universal Locking Plate System (originally cleared per K961421)

The DePuy Synthes 2.4 mm Universal Locking Plate System is a plate and screw system, that is intended for mandible trauma and reconstruction procedures.

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)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Mandibular Modular Fixation System (originally cleared per K954385)

The DePuy Synthes Mandibular Modular Fixation System is a plate and screw system, manufactured from commercially pure titanium, and is intended for use in:
• Oral, maxillofacial surgery: trauma; surgical correction of dentofacial deformities; reconstructive surgery; and 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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510(k) Number *(if known)*
K192655

Device Name
DePuy Synthes Maxillofacial Portfolio – MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Maxillofacial Titanium Micro Set (originally cleared per K912932)

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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1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes MatrixWAVE MMF System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K141165 MatrixWAVE MMF System

1.4. Device Description

The DePuy Synthes MatrixWAVE MMF is a bone-borne maxillomandibular fixation (MMF) system that consists of wave shaped plates (made from commercially pure Titanium) that are attached to the dental arches with self-drilling locking screws (made from Titanium alloy, Ti-6Al-7Nb). The system is intended for temporary stabilization of mandibular and maxillary fractures and osteotomies to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (approximately 6-8 weeks). The dental arches are brought into occlusion by wiring around the plate hooks and/or accessible screw heads.

1.5. Indications for Use

The DePuy Synthes MatrixWAVE MMF System is indicated for the temporary treatment of mandibular and maxillary fractures and osteotomies in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes MatrixWAVE MMF 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K141165
For the temporary treatment of mandibular and maxillary fractures and osteotomies in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.	For the temporary treatment of mandibular and maxillary fractures and osteotomies in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

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Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
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Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes MatrixMANDIBLE Plate and Screw System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K121574 MatrixMANDIBLE Plate and Screw System

1.4. Device Description

The DePuy Synthes MatrixMANDIBLE Plate and Screw System consists of a variety of plates offered in multiple shapes and sizes and a variety of screws offered in multiple diameters and lengths to meet the anatomical needs of the patient. System implants are manufactured in either titanium or titanium alloy and are intended for single use only.

The DePuy Synthes MatrixMANDIBLE screws that are the subject of this premarket notification are made from titanium alloy (Ti-6A1-7Nb) and are available in a diameter of 2.0 mm and lengths ranging from 4 mm to 8 mm, and have a thread pitch of 0.5 mm. These screws work with all plates within the DePuy Synthes MatrixMANDIBLE Plate and Screw System.

These devices are offered, non-sterile and must be sterilized prior to use. DePuy Synthes MatrixMANDLBLE screws are intended for single use.

1.5. Indications for Use

The DePuy Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery:
• Trauma
• Reconstructive surgery
• Orthognathic surgery (surgical correction of dentofacial deformities)

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes MatrixMANDIBLE Plate and Screw 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K121574
For oral, maxillofacial surgery: • Trauma • Reconstructive surgery • Orthognathic surgery (surgical correction of dentofacial deformities)	For oral, maxillofacial surgery: • Trauma • Reconstructive surgery • Orthognathic surgery (surgical correction of dentofacial deformities)

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
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Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes MatrixMANDIBLE Plate and Screw System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K113567 MatrixMANDIBLE Plate and Screw System

1.4. Device Description

The DePuy Synthes MatrixMANDIBLE Plate and Screw System consists of a variety of plates offered in multiple shapes and sizes and a variety of screws offered in multiple diameters and lengths to meet the anatomical needs of the patient.

This submission pertains to 1.5 mm thick MatrixMANDIBLE Reconstruction Plates, which are available as left and right single angle reconstruction plates and in three sizes of double angle reconstruction plates. These plates are made from pure titanium and may be offered sterile or non-sterile (non-sterile implants must be sterilized prior to use).

DePuy Synthes MatrixMANDIBLE 1.5 mm thick reconstruction plates are intended for single use only.

1.5. Indications for Use

The DePuy Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery:
• Trauma
• Reconstructive surgery
• Orthognathic surgery (surgical correction of dentofacial deformities)

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes MatrixMANDIBLE Plate and Screw 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K113567
For oral, maxillofacial surgery: • Trauma • Reconstructive surgery • Orthognathic surgery (surgical correction of dentofacial deformities)	For oral, maxillofacial surgery: • Trauma • Reconstructive surgery • Orthognathic surgery (surgical correction of dentofacial deformities)

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

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DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Dentoalveolar Bone Fixation System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K102656 Synthes Dentoalveolar Bone Fixation System

1.4. Device Description

The DePuy Synthes Dentoalveolar Bone Fixation System is a plate, mesh, and screw system intended to be implanted intraorally for use in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in reconstruction of maxillary and/or mandibular areas, including the dentoalveolar ridge.

Screws
The System includes 1.3 mm, 1.5 mm, and 2.0 mm diameter cortex screws in lengths from 3 mm to 20 mm. Screws are offered with both self-tapping and self drilling tips. Screws are manufactured from titanium alloy (Ti-6A1-7Nb).

Plates and Meshes
The System includes plates and meshes that come in a variety of configurations to accommodate various dentoalveolar defect sites. The plates attach to bone via titanium cortex screws. Plates and meshes are manufactured from commercially pure titanium.

1.5. Indications for Use

The DePuy Synthes Dentoalveolar Bone Fixation System is intended for use in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in reconstruction of maxillary and/or mandibular areas, including the dentoalveolar ridge.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Dentoalveolar Bone Fixation 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K102656
For use in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in reconstruction of maxillary and/or mandibular areas, including the dentoalveolar ridge.	For use in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in reconstruction of maxillary and/or mandibular areas, including the dentoalveolar ridge.

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
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Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes MatrixMANDIBLE Subcondylar Plates

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K091233 Synthes MatrixMANDIBLE Subcondylar Plates

1.4. Device Description

The DePuy Synthes MatrixMANDIBLE Subcondylar Plates are designed specifically to match the anatomy of the subcondylar region of the mandible. These plates are designed for use with DePuy Synthes MatrixMANDIBLE screws that come in multiple diameters and lengths to meet the anatomical needs of the patient. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

1.5. Indications for Use

The DePuy Synthes MatrixMANDIBLE Subcondylar Plates are intended for oral, maxillofacial surgery; trauma and reconstructive surgery, specifically for fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes MatrixMANDIBLE Subcondylar Plates. 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K091233
For oral, maxillofacial surgery; trauma and reconstructive surgery, specifically for fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.	For oral, maxillofacial surgery; trauma and reconstructive surgery, specifically for fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes MatrixMANDIBLE Preformed Reconstruction Plates

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K091144 Synthes MatrixMANDIBLE Performed Reconstruction Plates

1.4. Device Description

The DePuy Synthes MatrixMANDIBLE Preformed Reconstruction Plates are anatomically contoured to match the body and angle regions of the mandible in most patients. These plates are designed for use with DePuy Synthes MatrixMANDIBLE screws that come in multiple diameters and lengths to meet the anatomical needs of the patient. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

1.5. Indications for Use

The DePuy Synthes MatrixMANDIBLE Preformed Reconstruction Plates are intended for use in oral and maxillofacial surgery, trauma and reconstructive surgery. This includes primary

mandibular reconstruction, comminuted fractures and temporary bridging pending delayed secondary reconstruction, including fractures of edentulous and/or atrophic mandibles, as well as unstable fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes MatrixMANDIBLE Preformed Reconstruction Plates. 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K091144
For use in oral and maxillofacial surgery, trauma and reconstructive surgery. This includes primary mandibular reconstruction, comminuted fractures and temporary bridging pending delayed secondary reconstruction, including fractures of edentulous and/or atrophic mandibles, as well as unstable fractures.	For use in oral and maxillofacial surgery, trauma and reconstructive surgery. This includes primary mandibular reconstruction, comminuted fractures and temporary bridging pending delayed secondary reconstruction, including fractures of edentulous and/or atrophic mandibles, as well as unstable fractures.

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes MatrixORTHOGNATHIC Plating System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K083388 Synthes MatrixORTHOGNATHIC Plating System

1.4. Device Description

The DePuy Synthes MatrixORTHOGNATHIC Plating System consists of a variety of plates that come in a variety of shapes and sizes to meet the anatomical needs of the patient. This system is designed for use with DePuy Synthes Matrix screws. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

1.5. Indications for Use

The DePuy Synthes MatrixORTHOGNATHIC Plating System is intended for use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and

selective orthognathic surgery of the maxilla, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults.

Specific Indications for Use:

- Fractures of the midface and maxillofacial skeleton
- LeFort I osteotomies, sagittal split osteotomies and genioplasties
- Orthognathic surgery including reconstructive procedures

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes MatrixORTHOGNATHIC Plating 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K083388
For use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults. Specific Indications for Use: • Fractures of the midface and maxillofacial skeleton • LeFort I osteotomies, sagittal split osteotomies and genioplasties • Orthognathic surgery including reconstructive procedures	For use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults. Specific Indications for Use: • Fractures of the midface and craniofacial skeleton • LeFort I osteotomies, sagittal split osteotomies and genioplasties • Orthognathic surgery including reconstructive procedures

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes MatrixMANDIBLE Plate and Screw System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K082335 Synthes MatrixMANDIBLE Plate and Screw System

1.4. Device Description

The DePuy Synthes MatrixMANDIBLE Plate and Screw System incorporates small, medium and large plates designed so all plates accept all system screws. The plates are available in various shapes and thicknesses and accept self-tapping and self-drilling cortex and locking screws. The implants are manufactured from titanium.

1.5. Indications for Use

The DePuy Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes MatrixMANDIBLE Plate and Screw 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K082335
For oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).	For oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

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Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Craniofacial Plate and Screw System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K080331 Synthes Craniofacial Plate and Screw System

1.4. Device Description

The DePuy Synthes Orbital Plates, components of the Synthes Craniofacial Plate and Screw System, consist of anatomically shaped orbital plates that come in various sizes and configurations to fit the patient anatomy. These devices are designed for use with DePuy Synthes craniofacial bone screws commercially available in the U.S. System components are manufactured in titanium and are intended for single use only.

1.5. Indications for Use

The DePuy Synthes Craniofacial Plate and Screw System 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 Craniofacial Plate and Screw 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K080331
For use in selective trauma of the midface and maxillofacial skeleton, maxillofacial surgery, reconstructive procedures and selective orthognathic surgery of the maxilla and chin.	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. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

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1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: The DePuy Synthes MatrixMANDIBLE Plate and Screw System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K063790 The Synthes MatrixMANDIBLE Plate and Screw System

1.4. Device Description

The DePuy Synthes MatrixMANDIBLE Plate and Screw System is the next generation of Synthes (USA) fixation systems for the mandible. The system incorporates small, medium, and large plates designed so that all plates accept all system screws. The plates are available in various shapes and thicknesses, and accept self-tapping cortex and locking screws. The implants are manufactured from CP titanium and titanium alloy.

1.5. Indications for Use

The DePuy Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the The DePuy Synthes MatrixMANDIBLE Plate and Screw 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K063790
For oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).	For oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Craniofacial Plate and Screw System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K050608 Synthes (USA) Craniofacial Plate and Screw System

1.4. Device Description

The DePuy Synthes Craniofacial Plate and Screw System consist of plates and meshes that come in a variety of shapes and sizes to meet the anatomical needs of the patient. This system is designed for use with 1.8 mm screws and 2.1 mm emergency screws. The screws will be used with Synthes 1.8 mm hexagonal screwdriver blades. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

1.5. Indications for Use

The DePuy Synthes Craniofacial Plate and Screw System 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 Craniofacial Plate and Screw 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K050608
For use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	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. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Neuro Plate and Screw System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K042365 Synthes (USA) Neuro Plate and Screw System

1.4. Device Description

DePuy Synthes Neuro Plate and Screw System consists of plates, burr hole covers, and meshes that come in a variety of shapes and sizes to meet the anatomical needs of the patient. This system is designed for use with 1.8 mm screws and 2.1 mm emergency screws. The screws will be used with Synthes 1.8 mm hexagonal screwdriver blades. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

1.5. Indications for Use

DePuy Synthes Neuro Plate and Screw System 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 Neuro Plate and Screw 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K042365
For use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	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. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K033121 Synthes (USA) 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates

1.4. Device Description

The DePuy Synthes 1.3 & 1.5 mm Contourable Ti. Mesh Plates come in a variety of shapes and sizes to meet the anatomical need of the patient. The plates are sterile/non-sterile and for single use only.

1.5. Indications for Use

The DePuy Synthes 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates are 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 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates. 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K033121
For use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	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. Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

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1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Orbital Plates

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K031761 Synthes (USA) New/Sterial Orbital Plates

1.4. Device Description

The DePuy Synthes Orbital Plates come in a variety of shapes and sizes to meet the anatomical need of the patient. The plates are sterile/non-sterile and for single use only.

1.5. Indications for Use

The DePuy Synthes Craniofacial Plates are 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 Orbital Plates. 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K031761
For use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	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. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

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Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Low Profile Neuro System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K022012 Synthes Low Profile Neuro System

1.4. Device Description

The DePuy Synthes Low Profile Neuro System consists of titaniurn plates, meshes, and screws in a variety of shapes and sizes designed for various maxillofacial procedures.

1.5. Indications for Use

The DePuy Synthes Low Profile Neuro System 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. 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K022012
For use in selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	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. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Midface Distractor

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K022005 Synthes Midface Distractor

1.4. Device Description

The DePuy Synthes Midface Distractor is a maxillofacial distraction device consisting of two telescoping components with attached footplates. The device is intended to be placed subcutaneously with an anterior footplate fastened to the lateral orbital rim, extending down to the maxilla and spanning the zygomaticomaxillary suture; and a posterior footplate fastened to the temporal region of the cranium. The plates are fixed to the bone through unthreaded screw holes using 1.5 mm or 2.0 mm Cortex screws.

1.5. Indications for Use

The DePuy Synthes Midface Distractor is intended for use in adult and pediatric populations for the treatment of midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of the midfacial bones.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Midface 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K022005
For use in adult and pediatric populations for the treatment of midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of the midfacial bones.	For use in adult and pediatric populations for the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as syndromic craniosynostosis and midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones.

1.7. Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 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 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.

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

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Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Translating Maxillary Distractor

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K020505 Synthes (USA) Translating Maxillary Distractor

1.4. Device Description

The DePuy Synthes Translating Maxillary Distractor is an intra-oral distraction device. It features a distractor body with two adjustable footplate components, each with contourable legs having screw holes that are fixed to the bone via 2.0 mm or 2.4 mm cortex screws.

1.5. Indications for Use

The DePuy Synthes Translating Maxillary 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 in adult and pediatric populations.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Translating Maxillary 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K020505
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 in adult and pediatric populations.	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 in adult and pediatric populations.

1.7. Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Translating Maxillary 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 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.

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

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Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Midface Distractor

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K010499 Synthes (USA) Midface Distractor

1.4. Device Description

The DePuy Synthes Midface Distractor is a maxillofacial distraction device consisting of two telescoping components with attached footplates. The device is intended to be placed subcutaneously with an anterior footplate fastened to the lateral orbital rim, extending down to the maxilla and spanning the zygomaticomaxillary suture; and a posterior footplate fastened to the temporal region of the cranium. The plates are fixed to the bone through unthreaded screw holes using 1.5 mm or 2.0 mm Cortex screws.

1.5. Indications for Use

The DePuy Synthes Midface Distractor is intended for use in adult and pediatric populations for the treatment of midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of the midfacial bones.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Midface 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K010499
For use in adult and pediatric populations for the treatment of midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of the midfacial bones.	For use in adult and pediatric populations for the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as syndromic craniosynostosis and midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones.

1.7. Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 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 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.

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

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1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Maxillary Distractor

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K003393 Synthes Maxillary Distractor

1.4. Device Description

The DePuy Synthes Maxillary Distractor is an intra-oral distraction device. It features two telescoping components, with contourable legs having screw holes, that are fixed to the bone via 2.0 mm or 2.4 mm cortex screws.

1.5. Indications for Use

The DePuy Synthes Maxillary 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 in adult and pediatric populations.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Maxillary 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K003393
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 in adult and pediatric populations.	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 in adult and pediatric populations.

1.7. Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Maxillary 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 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.

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

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Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Orbital Mesh Plates

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K001311 Synthes (USA) Orbital Mesh Plates

1.4. Device Description

The DePuy Synthes Orbital Mesh Plates have a semi-circular shape with a radially designed mesh pattern. Orbital Mesh Plates are available in 0.2, 0.3 and 0.4 mm profile thickness. Standard 1.0 mm screw holes positioned along the outer arc of the Orbital Mesh Plate accept 1.0 mm self-tapping bone screws and 1.2 mm emergency screws. Synthes Orbital Mesh Plates for the Midfacial System are provided nonsterile.

1.5. Indications for Use

The DePuy Synthes Orbital Mesh Plates for the Midfacial System are indicated 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 Orbital Mesh Plates. 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K001311
For the Midfacial System are indicated for selective trauma of the midface and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	For selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes 2.0 MM Locking Plate System (2.0 LPS)

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K974555 Synthes 2.0 MM Locking Plate System (2.0 LPS)

1.4. Device Description

The DePuy Synthes 2.0 Locking Plate System consists of five different types of plates and two screws, as follows: 2.0 Straight Locking Plates, 2.0 Crescent Locking Plates, 2.0 Atrophic Locking Plates, 2.0 Reconstruction Locking Plates, 2.0 Specialty Plates (Y- and L-), and 1.5 mm and 2.0 mm Self-drilling Locking Screws.

The plates feature a threaded screw hole which accepts a locking screw with a mating external thread on the screw head. Engaging these screw threads fixes the screw to the plate thereby reducing the likelihood of screw loosening and improving the screw to plate stability of the implant system.

1.5. Indications for Use

The Depuy Synthes 2.0 LPS is intended for oral, maxillofacial surgery: trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.0 MM Locking Plate System (2.0 LPS). 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K974555
For oral, maxillofacial surgery: trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).	For oral, maxillofacial surgery: trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes 2.4 MM Universal Locking Plate System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K961421 Synthes 2.4 MM Universal Locking Plate System

1.4. Device Description

The DePuy Synthes 2.4 mm Universal Locking Plate System plates are designed to accept the 2.4 mm – 3.0 mm diameter locking/non-locking screws.

1.5. Indications for Use

The DePuy Synthes 2.4 mm Universal Locking Plate System is a plate and screw system, that is intended for mandible trauma and reconstruction procedures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 2.4 MM Universal Locking Plate 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K961421
For mandible trauma and reconstruction procedures.	For mandible trauma and reconstruction procedures.

1.7. Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 2.4 MM Universal Locking Plate System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The DUKE model places devices in the clinically relevant anatomic position. The DUKE results will be used for labeling of RF heating.

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

Date Prepared: December 23, 2019

1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Mandibular Modular Fixation System

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K954385 Synthes Mandibular Modular Fixation System

1.4. Device Description

The DePuy Synthes Mandibular Modular Fixation System is a plate and screw system manufactured from titanium. The plates are available in a variety of shapes and sizes, and attach to bone via 2.0 mm, 2.4 mm or 2.7 mm screws.

1.5. Indications for Use

The DePuy Synthes Mandibular Modular Fixation System is a plate and screw system, manufactured from commercially pure titanium, and is intended for use in:

- Oral, maxillofacial surgery: trauma; surgical correction of dentofacial deformities; reconstructive surgery; and 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 Mandibular Modular Fixation 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K954385
For use in: • Oral, maxillofacial surgery: trauma; surgical correction of dentofacial deformities; reconstructive surgery; and maxillofacial surgery	For use in: • Oral, maxillofacial surgery: trauma; surgical correction of dentofacial deformities; reconstructive surgery; and craniofacial surgery • ENT: trauma of the nasal bones Neurosurgery: osteosynthesis of the cranial bones.

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.

1. 510(k) Summary

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1.1. Submitter

Primary Contact:
Satapa Dhamankar
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: 610-719-6574
Email: sdhamank@its.jnj.com

Alternate Contact:
Jeffrey Krawiec, PhD
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5356
Email: jkrawiec@its.jnj.com

1.2. Device

Trade Name: DePuy Synthes Maxillofacial Portfolio – MR Conditional

Name of Device: DePuy Synthes Maxillofacial Titanium Micro Set

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3. Predicate Device

K912932 Synthes Maxillofacial Titanium Micro Set

1.4. Device Description

The DePuy Synthes Maxillofacial Titanium Micro set consists of titanium bone plates (shapes include L,Y,H,T, Double-Y, Mesh and Straight) and self-tapping screws.

1.5. Indications for Use

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 Maxillofacial Titanium Micro Set. 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, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

K192655	K912932
General indications: • Maxillofacial surgery	Specific Indications: • Nasoethmoidal fractures • Infraorbital area fractures • Frontal sinus wall Fractures • Infant craniofacial surgery General indications: • Maxillofacial surgery • Neurosurgery • Hand surgery

1.7. Performance Testing

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

1.8. Conclusion

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, are substantial equivalent to the primary predicate device.