September 18, 2020

Synthes (USA) Products LLC
Jeffrey Krawiec
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K192702
Trade/Device Name: DePuy Synthes Craniomaxillofacial Neuro Devices - MR Conditional
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN, GXR, GWO, JEY, DZL, MQN
Dated: August 19, 2020
Received: August 20, 2020

Dear Jeffrey Krawiec:

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

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

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

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*

K192702

Device Name
DePuy Synthes Maxillofacial Titanium Micro Set - MR Conditional

Indications for Use *(Describe)*

Neuro:
- Neurosurgery
- Nasoethmoidal fractures
- Infraorbital area fractures
- Frontal sinus wall Fractures
- Infant craniofacial surgery

Dental:
- 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)*

K192702

Device Name
DePuy Synthes Mandibular Modular Fixation System - MR Conditional

Indications for Use *(Describe)*

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

• Neurosurgery: osteosynthesis of the cranial 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)*

K192702

Device Name

DePuy Synthes Single Vector Distractor with Detachable Feet – MR Conditional

Indications for Use *(Describe)*

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

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

Neuro: The DePuy Synthes Single Vector Distractor with Detachable Feet can be used for stabilization and advancement of the mid-face, in which a deficiency of mid-facial bone requires gradual bone distraction. Such deficiencies include, but are not limited to Plagiocephaly, Trigonocephaly, Scaphocephaly, and Brachycephaly.

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)*

K192702

Device Name

DePuy Synthes Cranial Tube Clamp - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Cranial Tube Clamp is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure.

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)*

K192702

Device Name
DePuy Synthes Low Profile Neuro System - MR Conditional

Indications for Use *(Describe)*

Dental: 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.

Neuro: The DePuy Synthes Low Profile Neuro System is intended for cranial closure and/or bone fixation, craniotomies, cranial trauma repair and reconstruction.

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

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

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510(k) Number *(if known)*

K192702

Device Name
DePuy Synthes Low Profile Neuro System - 3 mm Screws – MR Conditional

Indications for Use *(Describe)*

Dental: 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.

Neuro: The DePuy Synthes Low Profile Neuro System is intended for cranial closure and/or bone fixation, craniotomies, cranial trauma repair and reconstruction.

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

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

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510(k) Number *(if known)*

K192702

Device Name

DePuy Synthes 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates - MR Conditional

Indications for Use *(Describe)*

Dental: 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.

Neuro: The DePuy Synthes 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates are intended for use in selective trauma of the craniofacial skeleton and craniofacial 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)*

K192702

Device Name
DePuy Synthes External Midface Distractor – MR Conditional

Indications for Use *(Describe)*

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

Neuro: The DePuy Synthes External Midface Distractor is intended for use in craniofacial surgery and reconstructive procedures. Specifically, it is intended for distraction of the cranium utilizing a monobloc osteotomy in adult and pediatric populations where gradual bone distration is required.

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

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

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510(k) Number *(if known)*

K192702

Device Name

DePuy Synthes 1.0/1.2 mm Craniofacial Screws – MR Conditional

Indications for Use *(Describe)*

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

Neuro:

- Nasoethmoidal fractures
- Infraorbital area fractures
- Frontal sinus wall fractures
- Infant craniofacial surgery

Dental:

- 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)*

K192702

Device Name
DePuy Synthes Neuro Plate and Screw System - MR Conditional

Indications for Use *(Describe)*

Dental: 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.

Neuro: DePuy Synthes Neuro Plate and Screw System is intended for use in fixation of the cranial bones in procedures such as reconstruction, fracture repair, craniotomies, and osteotomies.

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)*

K192702

Device Name
Modification to DePuy Synthes Low Profile Neuro System - MR Conditional

Indications for Use *(Describe)*

Dental: 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.

Neuro: The DePuy Synthes Low Profile Neuro System is intended for cranial closure and/or bone fixation, craniotomies, cranial trauma repair and reconstruction.

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

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

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Device Name

DePuy Synthes Craniofacial Plate and Screw System - MR Conditional

Indications for Use *(Describe)*

Dental: 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.

Neuro: The DePuy Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the craniofacial skeleton and craniofacial 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)*

K192702

Device Name

DePuy Synthes Craniomaxillofacial Distraction System (CMF Distraction System) – MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device.

The DePuy Synthes CMF Distraction System is indicated for correction of congenital deficiencies or post-traumatic defects of the cranium, where gradual bone distraction is required in adults and pediatric patients.

Cranium

The 1.5 mm and 2.0 mm mesh and cloverleaf footplates and screws are intended for infants, children, adolescents, and adults.

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

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

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510(k) Number *(if known)*

K192702

Device Name
DePuy Synthes MatrixNEURO Cranial Plating System - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes MatrixNEURO Cranial Plating System is intended for use in fixation of the cranial bones in procedures such as reconstruction, fracture repair, craniotomies, and osteotomies.

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)*
K192702

Device Name
DePuy Synthes MatrixNEURO Preformed Mesh (Part of the MatrixNEURO Cranial Plating System) - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes MatrixNEURO Preformed Mesh is intended for use in fixation of the cranial bones in procedures such as reconstruction, fracture repair, craniotomies, and osteotomies.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary

Date Prepared: August 19, 2020

1.1 Submitter

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1.2 Device

Name of Device: DePuy Synthes Maxillofacial Titanium Micro Set – MR Conditional

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

Neuro:

- Neurosurgery
- Nasoethmoidal fractures
- Infraorbital area fractures
- Frontal sinus wall Fractures
- Infant craniofacial surgery

Dental:

- 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.

1.7 Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Maxillofacial Titanium Micro Set 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, raise no new questions of safety or efficacy.

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1.2 Device

Name of Device: DePuy Synthes MAandibular Modular Fixation System – MR Conditional

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
- Neurosurgery: osteosynthesis of the cranial bones.

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.

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

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1.2 Device

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

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

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3 Predicate Device

K981075 Synthes (USA) Single Vector Distractor with Detachable Feet

1.4 Device Description

The DePuy Synthes Single Vector Distractor with Detachable Feet is a subcutaneous bone distractor activated by a drive component. It features two telescoping components activated by a jack screw, fixed to the bone with bone screws. Bone lengthening and distraction are achieved by gradually activating the device. Upon removal, the telescoping components and jack screw are disengaged and removed, leaving the subcutaneous foot plates in the patient.

1.5 Indications for Use

Dental: The DePuy Synthes Single Vector Distractor with Detachable Feet is intended for use as a bone stabilizer and lengthener for conditions such as mandibular hypoplasia or posttraumatic defects of the mandible, where gradual bone distraction is required. The device is ideal for treating fonns of clefts of the lip and palate, and congenital mandibular hypoplasia, such as

Hemifacial Microsomia, Treacher Collins Syndrome, Nagers Syndrome, Pierre Robin Syndrome, Goldenhar Syndrome, Apert Syndrome, and Crouzon Syndrome.

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

Neuro: The DePuy Synthes Single Vector Distractor with Detachable Feet can be used for stabilization and advancement of the mid-face, in which a deficiency of mid-facial bone requires gradual bone distraction. Such deficiencies include, but are not limited to Plagiocephaly, Trigonocephaly, Scaphocephaly, and Brachycephaly.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Single Vector Distractor with Detachable Feet. 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.

1.7 Performance Testing

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

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, raise no new questions of safety or efficacy.

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1.2. Device

Name of Device: DePuy Synthes Cranial Tube Clamp - MR Conditional

Classification Name(s): Plate, Cranioplasty, Preformed, Non-Alterable

Regulatory Class: Class II, §882.5330

Product Code(s): GXN

1.3. Predicate Device

K992000 Synthes Cranial Tube Clamp

1.4. Device Description

The DePuy Synthes Cranial Flap Tube Clamp consists of two clamp discs with a clamp shaft in between the discs. The clamp shaft consists of a 1.6 mm tube which is secured to the bottom disc. The top disc has a thickness of 0.4 mm and the plate diameters range from 8.0 to 20. mm.

1.5. Intended Use

The DePuy Synthes Cranial Tube Clamp is intended to reattach a cranial bone flap to the surrounding Cranium after a craniotomy procedure.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Cranial Tube Clamp. 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.

1.7. Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Cranial Tube Clamp 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, raise no new questions of safety or efficacy.

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1.2 Device

Name of Device: DePuy Synthes Low Profile Neuro System – MR Conditional

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 cranio-facial procedures.

1.5 Indications for Use

Dental: 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.

Neuro: The DePuy Synthes Low Profile Neuro System is intended for cranial closure and/or bone fixation, craniotomies, cranial trauma repair and reconstruction.

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.

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.

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1.2. Device

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

Classification Name(s): Screw, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZL

1.3. Predicate Device

K031807 Synthes Low Profile Neuro System - 3 mm Screws

1.4. Device Description

Synthes ø1.6 mm Low Profile Neuro System self-drilling, self·tapping, and ø1.9 mm emergency self-tapping screws in 3 mm lengths are to be added to the system.

1.5. Indications for Use

Dental: 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.

Neuro: The DePuy Synthes Low Profile Neuro System is intended for cranial closure and/or bone fixation, craniotomies, cranial trauma repair and reconstruction.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Low Profile Neuro System - 3 mm Screws. 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.

1.7. Performance Testing

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

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

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1.2 Device

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

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3 Predicate Device

K033121 1.3 & 1. 5MM 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

Dental: 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.

Neuro: The DePuy Synthes 1.3 & 1.5 mm Contourable Titanium (Ti.) Mesh Plates are intended for use in selective trauma of the craniofacial skeleton and craniofacial surgery.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 1.3 & 1.5mm 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.

1.7 Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 1.3 & 1.5mm 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

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1.2. Device

Name of Device: DePuy Synthes External Midface Distractor - MR Conditional

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

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3. Predicate Device

K040083 Synthes External Midface Distractor

1.4. Device Description

The DePuy Synthes External Midface Distractor is an external distraction osteogenesis device that attaches to the cranium and midface and is used to gradually lengthen the midface at the LeFort I, II, and III levels (including monobloc). The device consists of an external headframe, a central adjustment mechanism, a veridical central rod, horizontal crosspieces containing distraction screws, and separate footplates assemblies that attach to the zygoma and maxilla.

1.5. Indications for Use

Dental: The DePuy Synthes External Midface Distractor is intended for use in maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is intended for distraction of the maxilla utilizing a LeFort I osteotomy, the midface

utilizing a LeFort II or III osteotomy in adult and pediatric populations where gradual bone distraction is required.

Neuro: The DePuy Synthes External Midface Distractor is intended for use in craniofacial surgery and reconstructive procedures. Specifically, it is intended for distraction of the cranium utilizing a monobloc osteotomy in adult and pediatric populations where gradual bone distration is required.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes External Midface Distractor. 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.

1.7. Performance Testing

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

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1.2 Device

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

Classification Name(s): Screw, Fixation, Intraosseous

Regulatory Class: Class II; 872.4880

Product Code(s): DZL

1.3 Predicate Device

K041887 Synthes (USA) 1.0/1.2 mm Craniofacial Screws

1.4 Device Description

The DePuy Synthes 1.0/1.2 mm Craniofacial Screws are either self-drilling or self tapping, have a flat head profile with rounded edges with a cruciform recess, and are available in various lengths.

1.5 Indications for Use

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

Neuro:

- Nasoethmoidal fractures
- Infraorbital area fractures
- Frontal sinus wall fractures
- Infant craniofacial surgery

Dental:

- Maxillofacial surgery

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes 1.0/1.2 mm Craniofacial Screws. 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.

1.7 Performance Testing

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

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1.2 Device

Name of Device: DePuy Synthes Neuro Plate And Screw System – MR Conditional

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

Dental: 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.

Neuro: DePuy Synthes Neuro Plate and Screw System is intended for use in fixation of the cranial bones in procedures such as reconstruction, fracture repair, craniotomies, and osteotomies.

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.

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.

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1.2. Device

Name of Device: Modification to DePuy Synthes Low Profile Neuro System - MR Conditional

Classification Name(s): Cover, Burr Hole

Regulatory Class: Class II, §882.5250

Product Code(s): GXR

1.3. Predicate Device

K042986 Modification to Synthes (USA) Low Profile Neuro System

1.4. Device Description

The DePuy Synthes 1.6 mm burr hole covers come in various sizes to accommodate various fracture and osteotomy sites, have a low plate/screw head profile and use existing (previously cleared) 1.6 mm or 1.9 mm emergency self-tapping and self-drilling screws. The DePuy Synthes 1.6 mm Burr Hole Covers have 5 lobes to accommodate a shunt/drain and are available in 12, 15, 17, and 24 mm diameters with a plate thickness of 0.5 mm.

1.5. Intended Use

Dental: 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.

Neuro: The DePuy Synthes Low Profile Neuro System is intended for cranial closure and/or bone fixation, craniotomies, cranial trauma repair and reconstruction.

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.

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.

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Email: tshea@its.jnj.com

1.2 Device

Name of Device: DePuy Synthes Craniofacial Plate And Screw System – MR Conditional

Classification Name(s): Plate, Bone

Regulatory Class: Class II; 872.4760

Product Code(s): JEY

1.3 Predicate Device

K050608 Synthes 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

Dental: 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.

Neuro: The DePuy Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the craniofacial skeleton and craniofacial surgery.

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.

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, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: August 19, 2020

1.1 Submitter

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1.2 Device

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

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

Regulatory Class: Class II; 872.4760

Product Code(s): MQN

1.3 Predicate Device

K060138 Synthes (USA) Craniomaxillofacial Distraction System
K170818 DePuy Synthes Craniomaxillofacial Distraction (CMFD) System Cranial Indications

1.4 Device Description

DePuy Synthes Craniomaxillofacial (CMF) Distraction System is a modular distractor system intended for correction and reconstruction of the cranium in adults, adolescents, children, infants, and neonates. The distractor construct consists of the distractor body, footplates, extension arms, and bone screws, all of which are available in multiple configurations to meet patient and surgeon needs. The distractor body is first assembled with the desired footplates, and then the footplates are secured to bone using the bone screws. After implantation the distractor is activated through the rotation of an advancement/lead screw with an activation instrument percutaneously.

1.5 Indications for Use

The DePuy Synthes CMF Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device.

The DePuy Synthes CMF Distraction System is indicated for correction of congenital deficiencies or post-traumatic defects of the cranium, where gradual bone distraction is required in adults and pediatric patients.

Cranium
The 1.5 mm and 2.0 mm mesh and cloverleaf footplates and screws are intended for infants, children, adolescents, and adults.

1.6 Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Craniomaxillofacial Distraction System. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes, and indicate MR Conditional use by adding "- MR Conditional" to the name of each subject system.

1.7 Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Craniomaxillofacial Distraction System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and 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, raise no new questions of safety or efficacy.

1. 510(k) Summary

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1.2 Device

Name of Device: DePuy Synthes Craniofacial Plate And Screw System – MR Conditional

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

Dental: 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.

Neuro: The DePuy Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the craniofacial skeleton and craniofacial surgery.

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.

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, raise no new questions of safety or efficacy.

510(k) Summary

Date Prepared: August 19, 2020

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1.2. Device

Name of Device: DePuy Synthes MatrixNEURO Cranial Plating System - MR Conditional

Classification Name(s): Plate, Cranioplasty, Preformed, Alterable

Regulatory Class: Class II, §882.5320

Product Code(s): GWO

1.3. Predicate Device

K123723 Synthes MatrixNEURO Cranial Plating System

1.4. Device Description

The DePuy Synthes MatrixNEURO Cranial Plating System consists of bone fixation implants offered in a variety of shapes and sizes to meet the anatomical needs of the patient.

The reconstruction meshes are manufactured from titanium, are designed for use with DePuy Synthes MatrixNEURO Cranial Plating System screws, are offered sterile, and are intended for single use only.

The screws are manufactured from titanium alloy, are designed for use with DePuy Synthes MatrixNEURO plates, burr hole covers, and meshes, maybe be offered sterile or non-sterile, and are intended for single use only.

1.5. Intended Use

The DePuy Synthes MatrixNEURO Cranial Plating System is intended for use in fixation of the cranial bones in procedures such as reconstruction, fracture repair, craniotomies, and osteotomies.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes MatrixNEURO Cranial 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.

1.7. Performance Testing

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes MatrixNEURO Cranial 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, raise no new questions of safety or efficacy.

510(k) Summary

Date Prepared: August 19, 2020

1.1 Submitter

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1.2. Device

Name of Device: DePuy Synthes MatrixNEURO Preformed Mesh (Part of the MatrixNEURO Cranial Plating System) - MR Conditional

Classification Name(s): Plate, Cranioplasty, Preformed, Alterable

Regulatory Class: Class II, §882.5320

Product Code(s): GWO

1.3. Predicate Device

K140462 MatrixNEURO Preformed Mesh (Part of the MatrixNEURO Cranial Plating System)

1.4. Device Description

The DePuy Synthes MatrixNEURO Cranial Plating System consists of bone fixation implants offered in a variety of shapes and sizes to meet the anatomical needs of the patient.

The DePuy Synthes MatrixNEURO Preformed Meshes are precontoured to cover common cranial defects manufactured from grade 2 titanium that are designed for use with MatrixNEURO Cranial Plating System screws. The Preformed Meshes are offered sterile packed and are intended for single use only.

1.5. Intended Use

The DePuy Synthes MatrixNEURO Preformed Mesh is intended for use in fixation of the cranial bones in procedures such as reconstruction, fracture repair, craniotomies, and osteotomies.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes MatrixNEURO Preformed Mesh. 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.

1.7. Performance Testing

Non-clinical testing is provided to support the conditional safety of the MatrixNEURO Preformed Mesh 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, raise no new questions of safety or efficacy.