July 23, 2019

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

Re: K190963
Trade/Device Name: DePuy Synthes Craniomaxillofacial Sternal Devices - MR Conditional
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 19, 2019
Received: June 20, 2019

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure:

List of Cleared Devices in K190963

List of Cleared Devices in K190963

1. DePuy Synthes Sternal Fixation System- MR Conditional
2. DePuy Synthes MatrixRIB Fixation System- MR Conditional

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)*
K190963

Device Name
DePuy Synthes Sternal Fixation System - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Sternal Fixation System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

The DePuy Synthes Titanium 2.4 mm Universal Locking Plates (12, 13 and 20 hole) are indicated for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Contraindication: The DePuy Synthes Titanium 2.4 mm Universal Locking Plates are contraindicated for use in acute cardiac patients.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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)*
K190963

Device Name
DePuy Synthes MatrixRIB Fixation System - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes MatrixRIB Fixation System is indicated for use in skeletally mature patients with normal or osteoporotic bone for chest wall fixation, where:

DePuy Synthes MatrixRIB pre-contoured plates are indicated for the fixation, stabilization and reconstruction of:
- Rib fractures, fusions, osteotomies, and/or resections, including spanning gaps and/or defects
- Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

DePuy Synthes MatrixRIB straight plates are indicated for the fixation, stabilization and reconstruction of:
- Rib and sternum fractures, fusions, osteotomies, and/or resections, including spanning gaps and/or defects
- Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

DePuy Synthes MatrixRIB sternal plates, 2.8mm thickness, are indicated for the fixation, stabilization and reconstruction of:
- Sternum fractures, fusions, and/or osteotomies
- Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

The DePuy Synthes MatrixRIB intramedullary splints and the universal plate are indicated for the fixation and stabilization of ribs.

Contraindications:
The MatrixRIB Fixation System is contraindicated for:
- The fixation of the sternum in acute cardiac patients, due to the potential delay if emergent re-entry is required
- Screw attachment or fixation to the clavicle or spine
- Use in patients with latent or active infection, with sepsis, or who are unwilling or incapable of following postoperative care instructions.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

SYNTHES®

510(k) Summary

Date Prepared: July 17, 2019

1.1 Submitter

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

Alternate Contact:
Elizabeth Jacobs
Project Leader, Regulatory Affairs
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Sternal Fixation System - MR Conditional

Classification Name(s): Plate, Fixation, Bone; Screw, Fixation, Bone

Regulatory Class: Class II, §888.3030; §888.3040

Product Code(s): HRS; HWC

1.3. Predicate Device

K093772, K112689 DePuy Synthes Sternal Fixation System

1.4. Device Description

The DePuy Synthes Sternal Fixation System consists of machined titanium plates, a quick-release pin and 3.0 mm locking screws. The plates utilize screw fixation to create the construct.

1.5. Intended Use

The DePuy Synthes Sternal Fixation System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

The DePuy Synthes Titanium 2.4 mm Universal Locking Plates (12, 13 and 20 hole) are indicated for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Contraindication: The DePuy Synthes Titanium 2.4 mm Universal Locking Plates are contraindicated for use in acute cardiac patients

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the Sternal 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 Sternal 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, raise no new questions of safety or efficacy.

510(k) Summary

Date Prepared: July 17, 2019

1.1 Submitter

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

Alternate Contact:
Elizabeth Jacobs
Project Leader, Regulatory Affairs
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes MatrixRIB Fixation System - MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II, §888.3030

Product Code(s): HRS

1.3. Predicate Device

K161590, K190409 DePuy Synthes MatrixRIB Fixation System

1.4. Device Description

The proposed additions to the MatrixRIB Fixation System include sternal plates (straight plates, I-plates and T-plates) for fixation and reconstruction of the chest wall manufactured from commercially pure titanium (CP Ti Grade 4).

The previously cleared devices in the MatrixRIB Fixation System (K133616 and K081623) include locking plates, locking screws, and intramedullary splints for the fixation and stabilization of the chest wall for use in patients with normal or osteoporotic bone quality. These implants are available in multiple sizes and are manufactured from titanium alloy (Ti-6A-7Nb).

The MatrixRIB Self-Drilling Screws (K190409) are available as
• locking screws, for permanent fixation,

• and non-locking screws, for temporary fixation only.

The screws are provided in a range of lengths
• locking screws: 13 lengths from 8mm to 20mm, with 1mm increments
• non-locking screws: 2 lengths from 10mm to 12 mm, with 2 mm increments.

The major diameter of the bone thread is 2.7 mm, and all of the screws are manufactured from Titanium Alloy (Ti-6Al-7Nb).

1.5. Intended Use

The DePuy Synthes MatrixRIB Fixation System is indicated for use in skeletally mature patients with normal or osteoporotic bone for chest wall fixation, where:

DePuy Synthes MatrixRIB pre-contoured plates are indicated for the fixation, stabilization and reconstruction of:
- Rib fractures, fusions, osteotomies, and/or resections, including spanning gaps and/or defects
- Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

DePuy Synthes MatrixRIB straight plates are indicated for the fixation, stabilization and reconstruction of:
- Rib and sternum fractures, fusions, osteotomies, and/or resections, including spanning gaps and/or defects
- Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

DePuy Synthes MatrixRIB sternal plates, 2.8mm thickness, are indicated for the fixation, stabilization and reconstruction of:
- Sternum fractures, fusions, and/or osteotomies
- Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

The DePuy Synthes MatrixRIB intramedullary splints and the universal plate are indicated for the fixation and stabilization of ribs.

Contraindications:

The MatrixRIB Fixation System is contraindicated for:
- The fixation of the sternum in acute cardiac patients, due to the potential delay if emergent re-entry is required
- Screw attachment or fixation to the clavicle or spine
- Use in patients with latent or active infection, with sepsis, or who are unwilling or incapable of following postoperative care instructions.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the MatrixRIB 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 MatrixRIB 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, raise no new questions of safety or efficacy.