DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 3, 2016

Synthes (USA) Products LLC
Mr. Thomas Shea
Manager, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K161590
Trade/Device Name: MatrixRIB Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: September 23, 2016
Received: September 26, 2016

Dear Mr. Shea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161590

Device Name
MatrixRIB Fixation System

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.

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5. 510(k) Summary

Date Prepared: October 31, 2016

5.1. Submitter

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5.2. Device

Name of Device: MatrixRIB Fixation System
Common or Usual Name(s): Plate, Fixation, Bone
Classification Name(s): Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II; 888.3030
Product Code: HRS

5.3. Predicate Devices

Primary Predicate: Synthes MatrixRIB Fixation System (K133616)
Reference Devices: Synthes MatrixRIB Fixation System (K081623)
Synthes Sternal Fixation System (K112689, K093772, K081700, K050041, K010943)

5.4. Indications for 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

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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.

5.5. 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).

5.6. Comparison to Predicate Devices

Indications

The predicate devices are indicated for use in chest wall of the skeleton (i.e. ribs and sternum) for a variety of surgical applications (rib fixation, chest wall reconstruction, and chest wall deformity repair). The Indications for Use statement of the MatrixRIB Fixation System presented in this submission clearly defines the clinical application for each group of implant

devices within the system. The differences in the Indications statement for the proposed devices in comparison to the predicates do not constitute a new intended use not already addressed by the predicates.

Technological Similarities of the MatrixRIB Plates

- Same principles of operation as the existing MatrixRIB plates and Synthes Sternal Fixation System predicates, i.e. metallic plates that can be fixated to bone using screws.
- The plates have similar shapes compared to the predicates: T, I and straight plates.
- Similar sizes compared to the predicates; proposed plates are 2.8 mm thick and the Sternal Fixation System predicate plates are 3.0 mm thick.
- Proposed plates have the same locking screw hole design as the existing predicate MatrixRIB plates, and therefore are compatible with the existing MatrixRIB screws.
- The proposed plates are manufactured from the same material as the Synthes Sternal Fixation System predicate (CP Ti Grade 4).

Technological Differences of the MatrixRIB Plates

- The new sternal plates are 2.8 mm thick compared to the previously cleared MatrixRIB sternal plates (K133616) which are 2.0 mm thick.
- Most plates in the predicate Synthes Sternal Fixation System have an emergency release pin; the proposed MatrixRIB plates do not have an emergency release pin.
- The predicate plates can be cut intra-operatively to achieve the desired length where the proposed plates are not intended to be cut.

5.7. Non-clinical performance data

Non-clinical testing and analyses comparing the proposed devices to the predicates within this submission include:

- Intraoperative Contouring Dynamic Test Method
- Comparative Four Point Static Test Method

The non-clinical performance data demonstrates that the mechanical performance of the proposed MatrixRIB Fixation System is comparable to that of the predicates.

Bacterial Endotoxin Testing was conducted and met the specified endotoxin limits.

5.8. Clinical performance data

Clinical testing was not necessary for the determination of substantial equivalence.

5.9. Substantial Equivalence

The proposed devices have the same intended use as the predicate devices. The mechanical testing included in this submission demonstrates that:

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- Any differences in technological characteristics of the predicates do not raise any new questions of safety and effectiveness.
- The proposed devices are at least as safe and effective as the predicates.

It is concluded that the information provided in this submission supports substantial equivalence.

(end of summary)