May 9, 2024

Synthes GmbH
Georgina Mueller, PhD
Sr. Regulatory Affairs Program Lead
Luzernstrasse 21
Zuchwil, SO 4528
Switzerland

Re: K233967
Trade/Device Name: DePuy Synthes MatrixSTERNUM 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, HWC
Dated: April 9, 2024
Received: April 9, 2024

Dear Dr. Mueller:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Shumaya Ali, M.P.H.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233967

Device Name

DePuy Synthes MatrixSTERNUM Fixation System

Indications for Use *(Describe)*

The DePuy Synthes MatrixSTERNUM Fixation System is indicated for use in adults with normal bone quality.
MatrixSTERNUM Sternal Body Plates are indicated for internal fixation of bone discontinuities following sternotomy.
MatrixSTERNUM Thoracotomy Plates are indicated for internal fixation of bone and/or cartilage discontinuities following thoracotomy.

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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510(k) Summary

Sponsor	Synthes GmbH Georgina Mueller Luzernstasse 21 4528 Zuchwil, Switzerland Phone: +41 61 965 63 14
Date Prepared	May 3, 2024
Proprietary Name	DePuy Synthes MatrixSTERNUM Fixation System
Classification Name	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification	Plates Class II Regulation Number: 21 CFR 888.3030 (Primary) Product Code: HRS Screws Class II Regulation Number: 21 CFR 888.3040 Product Code: HWC
Predicate / Reference devices	Predicate for MatrixSTERNUM Sternal Body Plates and MatrixSTERNUM Screws: Biomet Microfixation Sternal Closure System (SternaLock Blu Primary Closure System), K161896 Predicate for MatrixSTERNUM Thoracotomy Plates and MatrixSTERNUM Screws: DePuy Synthes MatrixRIB Fixation System, K161590 / K190409 Reference Device for MatrixSTERNUM Sternal Body Plates: Ethicon Cerclage Wire (K946173)
Device Description	The DePuy Synthes MatrixSTERNUM Fixation System consists of two families of plates, namely the MatrixSTERNUM Sternal Body Plates and MatrixSTERNUM Thoracotomy Plates, and two families of screws, namely the MatrixSTERNUM Self-Drilling Locking and Non-Locking Screws.

	The DePuy Synthes MatrixSTERNUM Fixation System is intended for the stabilization and fixation of bones in the anterior chest wall. The subject plates are available in different shapes and sizes and are made from Titanium Alloy or commercially pure Titanium. The system also consists of non-implantable dedicated use screw guides, a screw guide handle, trays and modules, as well as general use instruments to be used as accessories with the subject implants.
Indications for Use	The DePuy Synthes MatrixSTERNUM Fixation System is indicated for use in adults with normal bone quality. MatrixSTERNUM Sternal Body Plates are indicated for internal fixation of bone discontinuities following sternotomy. MatrixSTERNUM Thoracotomy Plates are indicated for internal fixation of bone and/or cartilage discontinuities following thoracotomy.
Technological Characteristics	The design, features, and specifications of the subject and predicate devices are compared below. <u>MatrixSTERNUM Sternal Body Plates</u> • The range of plate shapes, sizes, and thicknesses of the subject devices are similar to those offered in the predicate devices. • The materials of both the subject and predicate devices are the same with plates offered in commercially pure titanium. • Subject and predicate plates and screws feature Locking Technology. The subject plates include locking holes that mate with locking screw heads, whereas the predicate plates have locking thread geometry cut into the plates by the screws during insertion. • The subject and predicate plates have varying screw holes; in number, type and diameter. The subject plate screw holes accommodate a 2.7mm diameter screw whereas the predicate plate screw holes accommodate both 2.4mm diameter and 2.7mm diameter screws. <u>MatrixSTERNUM Thoracotomy Plates</u> • The plate screw hole geometry and thickness of the subject devices are similar to those offered in the predicate devices. • The materials of both subject and predicate devices are the same with plates offered in titanium alloy. • Both subject and predicate devices have locking holes that mate with 2.7mm diameter screws with locking screw heads.

	• Additional features are found in the subject plates that are not found in the predicate plates.
	  ○ Subject plates include a straight bar region to span the bone discontinuity.
	  ○ Subject T-plates include a perpendicular region to span a bone discontinuity from sternum to rib.
	
	<u>MatrixSTERNUM Self-Drilling Locking and Non-Locking Screws</u>
	
	• The subject locking and non-locking self-drilling screws are of the same geometry and offered in the same lengths as the predicate locking and non-locking self-drilling screws.
	• The materials of both subject and predicate devices are the same with screws offered in titanium alloy. The anodization color varies between subject and predicate.
	• Subject and predicate locking screws have the same locking head geometry to mate with the locking plate threads.
	• Subject and predicate non-locking screws have the same head geometry to lag and temporarily fixate the plate to bone.

Non-clinical Performance Data	Mechanical performance evaluation and testing of constructs has been performed to compare: • The subject MatrixSTERNUM Sternal Body Plates to the predicate Biomet Microfixation Sternal Closure System; and • The subject MatrixSTERNUM Thoracotomy Plates to the predicate DePuy Synthes MatrixRIB Fixation System. This data supports that the subject devices do not raise any new issues of safety and effectiveness in terms of mechanical performance compared to the respective predicate devices. A magnetic resonance compatibility assessment has been performed to establish MR Conditional parameters for the subject DePuy Synthes MatrixSTERNUM Fixation System Plates and Screws. Endotoxin testing has been performed according to the LAL test method to establish that the sterile subject DePuy Synthes MatrixSTERNUM Fixation System Implants (Plates and Screws) meet the specified endotoxin requirement of 20EU/device.

	Biocompatibility evaluation and testing has been performed in accordance with ISO 10993-1 and it is concluded that the subject plates, screws, screw guides, screw guide handle, trays and modules part of the DePuy Synthes MatrixSTERNUM Fixation System are biologically safe when used as intended.
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	<u>MatrixSTERNUM Sternal Body Plates</u> The subject and the predicate devices share the same intended use, which is for the stabilization and fixation of the anterior chest wall, and are both intended to be used by surgeons within a health care facility. The subject device indications are a subset of the predicate Biomet Microfixation Sternal Closure System (K161896) indications. <u>MatrixSTERNUM Thoracotomy Plates</u> The subject devices' intended use is the stabilization and fixation of the anterior chest wall, whereas the predicate's intended use is the stabilization and fixation of the chest wall. The subject devices' intended use, therefore, falls within the same intended use as the predicates' intended use, as it is a subset thereof. Both subject and predicate devices are intended to be used by surgeons within a health care facility. The subject device indications are a subset of the predicate DePuy Synthes MatrixRIB Fixation System (K161590 / K190409) indications. The non-clinical performance data as well as the comparison of design features included in this premarket notification demonstrate that any differences in technological characteristics of the subject devices compared to the predicate devices do not raise any new issues of safety and effectiveness. It is concluded that the information provided herein supports substantial equivalence of the subject devices.