September 10, 2020

Prem Pisupati
Senior Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K201944
Trade/Device Name: DePuy Synthes 2.4mm Ti Self-Tapping MatrixMANDIBLE Screws (26-40mm)
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: August 10, 2020
Received: August 11, 2020

Dear Prem Pisupati:

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

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

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

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201944

Device Name
DePuy Synthes 2.4 mm Ti Self-Tapping MatrixMANDIBLE Screws (26 - 40mm)

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

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Sponsor	DePuy Synthes Prem Pisupati 1301 Goshen Parkway West Chester, PA USA Phone: 610-719-1019
Date Prepared	September 10, 2020
Proprietary Name	DePuy Synthes 2.4mm Ti Self-Tapping MatrixMANDIBLE screws (26-40mm)
Common Name	Bone Plate
Classification	Class II Regulation Number: 21 CFR 872.4760 Product Code: JEY
Predicate Device	Synthes MatrixMANDIBLE Plate and Screw System (K063790)
Reference Device	Synthes Mandibular Modular Fixation System (K954385) Synthes MatrixMANDIBLE Plate and Screw System (K121574)
Reason for Submission	To introduce a non-sterile packaged version of the 2.4mm Ti Self-Tapping MatrixMANDIBLE screws additional lengths (26mm – 40mm).
Device Description	The Synthes MatrixMANDIBLE Plate and Screw System consists of a variety of plates offered in multiple shapes and sizes and a variety of screws offered in multiple diameters and lengths to meet the anatomical needs of the patient. System implants are manufactured in either titanium or titanium alloy and are intended for single use only. The Synthes MatrixMANDIBLE screws that are the subject of this submission are made from titanium alloy (Ti-6Al-7Nb) and are available in a diameter of 2.4 mm and lengths ranging from 26-40mm, and have a thread pitch of 1.0 mm. These screws work with all plates within the MatrixMANDIBLE Plate and Screw system. These devices are offered non-sterile and must be sterilized before use. MatrixMANDIBLE screws are intended for single use only.
Indications for use	The DePuy Synthes MatrixMANDIBLE Plate and Screw System is intended for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities)

Contraindications	- Acute or chronic, local or systemic infections - Allergy to implant material - Insufficient bone quality to secure the implant
Comparison to Predicate	The subject device has the same intended use as the predicate device. The intended use of the subject system is a subset of the intended use of the reference device. The subject devices, predicate device and the reference device are metallic plates with a low-profile design intended for bone fracture fixation. Both subject, predicate and reference devices are compatible with the same screw types. The subject and predicate devices are made from Titanium Alloy (TAN). The subject devices present the following features that are not similar in the reference device: • Reference devices have a slightly larger screw head diameter and thread diameter than the subject devices • Reference devices core diameter is lower than the subject devices • Reference devices are manufactured from commercially pure Titanium, while the subject devices are manufactured from Titanium Alloy (TAN) It can be concluded that features of the subject device are substantially equivalent to the predicate and reference devices based on the similarities in intended use and design.
Non-clinical Performance Testing	Testing was performed per ASTM F543 to compare the proposed DePuy Synthes 2.4mm Ti Self-Tapping MatrixMANDIBLE screws to the reference device. This information supports that the mechanical performance of the subject devices is at least non-inferior to that of the reference device. Sterilization adoption evaluated the subject device design and materials and confirmed that the subject device does not present a new worst case and can therefore be adopted under existing Moist Heat sterilization validation. Packaging validation demonstrates that the bag LDPE on roll or PE tubing for the non-sterile version of the subject device can protect the non-sterile device during distribution and ensure product integrity. Biocompatibility evaluation confirms that the non-sterile packaged version of the subject device meets the requirements of ISO 10993-1 and that the proposed devices intended for direct contact with the human body present no toxicological risk.
Clinical Performance Data	Clinical data was not necessary for the determination of substantial equivalence.
Substantial	The subject device has the same indications for use, design, and material of manufacture as the predicate device. The subject devices will be available in

Equivalence	longer lengths than the predicate devices. The summary of verification and validation activities included in this submission support that the addition of a non-sterile version of the 2.4mm Ti Self-Tapping MatrixMANDIBLE screws do not raise any issues regarding safety and effectiveness. It is concluded that the information provided in this submission supports substantial equivalence.