July 24, 2020

DePuy Synthes
% Georgina Mueller
Regulatory Affairs Specialist II
Synthes GMBH
Luzernstrasse 21
Zuchwil, SO 4528
Switzerland

Re: K201321
Trade/Device Name: DePuy Synthes 2.7mm VA LCP Clavicle Plate 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: May 13, 2020
Received: May 18, 2020

Dear Georgina 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 (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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201321

Device Name

DePuy Synthes 2.7mm VA LCP Clavicle Plate System

Indications for Use *(Describe)*

The DePuy Synthes 2.7mm VA LCP Clavicle Plate System is indicated for fixation of fractures, osteotomies, and non-unions of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.

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."

510(k) Summary

Sponsor	DePuy Synthes Georgina Mueller 1301 Goshen Parkway West Chester, PA 19380 Phone: +41 61 965 63 14
Date Prepared	July 21, 2020
Proprietary Name	DePuy Synthes 2.7mm VA LCP Clavicle Plate System
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Classification	Class II Regulation Number: 21 CFR 888.3030 Product Code: HRS
Primary predicate device	Synthes LCP Reconstruction Plate 3.5 (K000684)
Secondary predicate device	Synthes 3.5mm LCP Clavicle Plate System (K111540)
Device Description	The DePuy Synthes 2.7mm VA LCP Clavicle Plate System consists of lateral, shaft and medial plates designed for temporary fixation, correction or stabilization of clavicle bones. The subject plates are available in various sizes in both sterile and non-sterile configurations and are available in stainless steel and titanium alloy. The system also consists of non-implantable templates that correspond to the implants. Templates are intended for implant size selection and are available in non-sterile.
Indications for use	Fixation of fractures, osteotomies, and non-unions of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.
Technological Characteristics	The design, features, and specifications of the subject and predicate devices are compared below. • The range of lengths and widths of the subject devices are similar to those offered in the predicate devices. The subject plates are slightly thinner than the predicate plates. • The materials of both the subject and predicate devices are the same for plates offered in stainless steel (i.e. 316L). The materials of the subject and primary predicate plates are similar; i.e. titanium alloy (TAN) and commercially pure Titanium, respectively. The materials for the subject and secondary predicate plates are the same, i.e. TAN. • Subject and predicate plates feature Locking and Compression Technology (LCP) and subject plates additionally feature Variable Angle (VA) technology to allow insertion of screws up to 15° angulation in addition to nominal angulation, whereas the predicate plates feature Locking Technology (LCP) only at nominal angulation. • The subject and predicate plates have varying screw holes; in number, type and diameter. The subject plates have Variable Angle locking and Combi holes whereas the predicate plates have Locking holes and Combi holes. The subject plate screw holes are 2.7mm diameter whereas the predicate plate screw holes are 3.5mm diameter. • All plates are compatible with Cortex Screws to ensure axial and plate-to-bone compression and with screws using locking technology to ensure angular stable fixation. Additional compatible screw types vary for subject (VA Locking, Metaphyseal) and

	predicate (Locking, Cancellous) plates, as do the screw diameters for subject plates (2.7mm) and predicate plates (3.5mm, 2.7mm, 2.4mm and 4.0mm). • Subject (Lateral and Shaft) and secondary predicate plates (Superior) feature K-wire holes for temporary fixation, whereas subject (Medial) and primary predicate plates do not feature suture or K-wire holes. Subject plates (Lateral) feature suture holes, which are not featured in either of the predicate plates. • Subject and secondary predicate plates are pre-contoured to accommodate for anatomical differences and available as mirrored plates dedicated for the left and right clavicle. Primary predicate plates are straight and can be used for left and right clavicle. All plates can be contoured intra-operatively and notches are featured to facilitate plate bending. • Subject plates and secondary predicate plates have a low-profile design to help avoid potential for soft tissue irritation and feature tapered tips (edges) to facilitate plate insertion. Primary predicate plates do not feature low-profile design or tapered tips (edges).
Non-clinical Performance Data	Static and cyclic mechanical testing of constructs has been performed to compare the subject DePuy Synthes 2.7mm VA LCP Clavicle Plates to the predicate DePuy Synthes 3.5mm LCP Reconstruction Plates. This information supports that the mechanical performance of the subject devices is at least equivalent to that of the predicate devices. Magnetic Resonance compatibility testing has been performed to establish MR Conditional parameters for the subject DePuy Synthes 2.7mm VA LCP Clavicle Plates. Endotoxin testing has been performed using to the LAL test method to establish that the sterile subject DePuy Synthes 2.7mm VA LCP Clavicle Plates 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 DePuy Synthes 2.7mm VA LCP Clavicle Plates are biologically safe when used as intended.
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	Both the subject and the predicate devices are intended for the use in temporary fixation, correction or stabilization of clavicle bones during open reduction internal fixation (ORIF) performed by surgeons within a health care facility. Plates are available sterile and non-sterile. Sterile plates are sterilized by gamma irradiation. The subject devices have similar indications to the primary predicate and fully align with the indications of the secondary predicate: fixation of fractures, osteotomies, and non-unions of the clavicle. The subject devices' patient target population includes both adolescence and adults consistent with the secondary predicate devices. No new issues of safety and effectiveness for the subject devices have been identified compared to the predicate devices. The non-clinical performance data as well as the comparison of indications and 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 questions of safety and effectiveness. It is concluded that the information provided herein supports substantial equivalence of the subject devices.