September 11, 2020

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

Re: K201959
Trade/Device Name: DePuy Synthes 2.7mm VA LCP Clavicle Hook 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: July 7, 2020
Received: July 14, 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,

for - 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)*

K201959

Device Name

DePuy Synthes 2.7mm VA LCP Clavicle Hook Plate System

Indications for Use *(Describe)*

The DePuy Synthes 2.7mm VA LCP Clavicle Hook Plate System is indicated for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

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

Sponsor	DePuy Synthes Georgina Mueller 1301 Goshen Parkway West Chester, PA 19380 Phone: +41 61 965 63 14
Date Prepared	September 3, 2020
Proprietary Name	DePuy Synthes 2.7mm VA LCP Clavicle Hook 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
Predicate device	Synthes 3.5mm LCP Clavicle Hook Plates (Synthes USA Clavicle Hook Plate; K061753)
Device Description	The DePuy Synthes 2.7mm VA LCP Clavicle Hook Plate System consists of the plate types Long, Short and Button which can be used to treat simple and complex clavicle fractures including malunions, non-unions and isolated ligamentous injuries of the AC joint. The subject plates are available in three hook depths, in left- and right-side versions, in both sterile and non-sterile configurations and are available in stainless steel and titanium. The system also consists of non-implantable templates that correspond to the implants. Templates are intended for implant size selection and are available non-sterile.
Indications for use	The DePuy Synthes 2.7mm VA LCP Clavicle Hook Plate System is indicated for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.
Technological Characteristics	The design, features, and specifications of the subject and predicate devices are compared below. • The range of plate lengths, thickness and hook depths of the subject devices are similar to those offered in the predicate devices. The subject plate hooks are angulated, whereas the predicate plate hooks are not. • The materials of both the subject and predicate devices are the same with plates offered in stainless steel and titanium (i.e. 316L and commercially pure titanium). • The subject and predicate plates have varying screw holes; in number, type and diameter. o 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. o 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. o 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 and 4.0mm).

	• Subject plates feature Suture / K-wire holes, whereas these are not featured in the predicate plates. • Both subject and predicate plates are pre-contoured to accommodate for anatomical differences, are available as mirrored plates dedicated for the left and right clavicle and are designed to allow intra-operative contouring. • Plates have a rounded shaft-profile to reduce prominence and feature tapered tips (edges) to facilitate plate insertion. Subject plates (long version only) feature notches to facilitate plate bending, whereas the predicate plates do not feature notches.
Non-clinical Performance Data	Mechanical performance testing of constructs has been performed to compare the subject DePuy Synthes 2.7mm VA LCP Clavicle Hook Plates to the predicate DePuy Synthes 3.5mm LCP Clavicle Hook Plates. This data supports that the mechanical performance of the subject devices is at least equivalent to that of the predicate devices. A magnetic resonance compatibility assessment has been performed to establish MR Conditional parameters for the subject DePuy Synthes 2.7mm VA LCP Clavicle Hook Plates. Endotoxin testing has been performed according to the LAL test method to establish that the sterile subject DePuy Synthes 2.7mm VA LCP Clavicle Hook 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 Hook 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 use in fixation of the clavicle and the acromioclavicular joint during open reduction internal fixation (ORIF) performed by surgeons within a health care facility. Subject plates are available sterile and nonsterile, whereas the predicate plates are available sterile only. Sterile plates for both subject and predicate are sterilized by gamma irradiation. The subject devices have the same indications as the predicate 3.5mm LCP Clavicle Hook Plates (K061753). 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.