December 16, 2020

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

Re: K203414
Trade/Device Name: DePuy Synthes 2.7mm VA LCP Clavicle Plate System, 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: November 16, 2020
Received: November 19, 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 Stereotaxic, Trauma
and Restorative 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203414

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203414

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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510(k) Summary

DePuy Synthes 2.7mm VA LCP Clavicle Plate System

Sponsor	DePuy Synthes Georgina Mueller 1301 Goshen Parkway West Chester, PA 19380 Phone: +41 61 965 63 14
Date Prepared	November 16, 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
Predicate device	DePuy Synthes 2.7mm VA LCP Clavicle Plate System (K201321)
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 device remain unchanged compared to the previously cleared version of this device cleared via K201321 (predicate device).
Non-clinical Performance Data	Non-clinical performance data was not necessary for the determination of substantial equivalence.

Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The following subject device characteristics remain unchanged compared to the previously cleared version of these devices (predicate): - 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. - 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. - Design, features, and specifications (technological characteristics) The subject devices have added contraindications compared to the predicate devices which has no contraindications. The differences in contraindications 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.

DePuy Synthes 2.7mm VA LCP Clavicle Hook Plate System

Sponsor	DePuy Synthes Georgina Mueller 1301 Goshen Parkway West Chester, PA 19380 Phone: +41 61 965 63 14
Date Prepared	November 16, 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	DePuy Synthes 2.7mm VA LCP Clavicle Hook Plate System (K201959)
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 device remain unchanged compared to the previously cleared version of this device cleared via K201959 (predicate device).
Non-clinical Performance Data	Non-clinical performance data was not necessary for the determination of substantial equivalence.
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The following subject device characteristics remain unchanged compared to the previously cleared version of these devices (predicate): - Intended for the 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 are sterilized by gamma irradiation. - Indicated for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint. - Design, features, and specifications (technological characteristics) The subject devices have revised contraindications compared to the compared to the predicate device. The differences in contraindications 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.