September 9, 2020

Synthes (USA) Products, LLC
Enrico Gindro
Regulatory Affairs Specilaist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K201578
Trade/Device Name: DePuy Synthes Variable Angle Locking Patella Plating 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: June 8, 2020
Received: June 11, 2020

Dear Enrico Gindro:

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, MPH
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)*

K201578

Device Name
DePuy Synthes Variable Angle Locking Patella Plating System

Indications for Use *(Describe)*

The DePuy Synthes Variable Angle Locking Patella Plating System is indicated for the fixation and stabilization of patellar fractures in normal and osteopenic bone in skeletally mature patients.

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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K201578 - 510(k) Summary

Sponsor	DePuy Synthes Enrico Gindro 1301 Goshen Parkway West Chester, PA 19380 Phone: +41 79 912 73 59
Date prepared	August 7, 2020
Proprietary name	DePuy Synthes Variable Angle Locking Patella Plating 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 2.4 mm / 2.7 mm Variable Angle LCP Forefoot / Midfoot System (K100776)
Device description	The DePuy Synthes Variable Angle Locking Patella Plating System is comprised of implants which will be placed on the anterior surface of the fractured patella to provide fixation during bone healing. The system offers three plate configurations, in two sizes, to provide fixation for various patella fracture patterns and are available in implant grade stainless steel and titanium. The system also consists of sterile, non-implantable templates that correspond to the implants. Templates are intended to help determine proper sizing and help predict contoured shape of the implant.
Indications for use	The DePuy Synthes Variable Angle Locking Patella Plating System is indicated for the fixation and stabilization of patellar fractures in normal and osteopenic bone in skeletally mature patients.
Contraindications	No contraindications specific to these devices.

Comparison to predicate	The subject device has the same intended use as the predicate device. The indications of the subject system are a subset of the indications of the predicate device. The subject devices and the predicate device are metallic plates with a low profile design intended for bone fracture fixation. Both subject and predicate device are anatomically contoured plates and are compatible with the same screw types. The subject devices present the following features that are not found in the predicate device: • Subject devices are offered in a range of configurations and sizes to accommodate patient anatomy and surgical need, whereas the predicate device is available in a single configuration to be shaped intraoperatively • Additional footprints shaped to the patellar anatomy to minimize cutting time in the OR • The core plate curvature is spherical in nature based on patellar anatomy to minimize intraoperative contouring time The subject devices are made from Stainless Steel (316L) or Commercially Pure Titanium, while the predicate device is made from Stainless Steel (316L) or Titanium Alloy (TAN). It can be concluded that features of the subject device are substantially equivalent to the predicate device based on the similarities in intended use and design.
Non-clinical performance data	Testing of constructs (plate with screws) under static and dynamic loading conditions have been performed to compare the proposed DePuy Synthes Variable Angle Locking Patella Plating System to the predicate device. This information supports that the mechanical performance of the subject devices is at least non-inferior to that of the predicate device. Magnetic Resonance compatibility testing has been performed to establish MR Conditional parameters for the subject DePuy Synthes Variable Angle Locking Patella Plating System. Endotoxin testing has been performed using to the LAL test method to establish that the subject DePuy Synthes Variable Angle Locking Patella Plating System meet the specified endotoxin requirement of 20 EU/device.
Clinical performance data	Clinical testing was not necessary for the determination of substantial equivalence.

Substantial equivalence	The subject device has the same intended use compared to the predicate device. 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 device compared to the predicate device 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.