March 26, 2021

Synthes (USA) products, LLC
Satapa Dhamankar
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K210205
Trade/Device Name: DePuy Synthes 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plates and Proximal Femur Hook Plates, DePuy Synthes 3.5 mm VA Locking Attachment Plate, DePuy Synthes 3.5 mm VA Locking PPFx Distal Femur Spanning Attachment Plates, DePuy Synthes 3.5 mm VA Locking PPFX Greater Trochanter Ring Attachment Plates, DePuy Synthes 3.5 mm VA Locking PPFX Greater Trochanter Hook Plates
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: January 25, 2021
Received: January 26, 2021

Dear Satapa Dhamankar:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210205

Device Name
DePuy Synthes 3.5/4.5 mm Variable Angle LCP Periprosthetic Proximal Femur Plating System

Indications for Use *(Describe)*

DePuy Synthes 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plates and Proximal Femur Hook Plates are indicated for the treatment of periprosthetic fractures and fractures in the presence of intramedullary implants in the proximal end segment and the proximal and middle 1/3 of the diaphyseal segment of the femur, and non-unions or malunions of such fractures, in adult patients, particularly in osteoporotic and osteopenic bone.

DePuy Synthes 3.5 mm VA Locking Attachment Plate is indicated to augment the stabilization of fractures, including periprosthetic fractures (Vancouver Type B when used with either the 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plate or Proximal Femur Hook Plate; Vancouver Type B and C when used with other DePuy Synthes LCP plates and VA-LCP plates) and fractures in the presence of intramedullary implants, in the femur, tibia, and humerus.

DePuy Synthes 3.5 mm VA Locking PPFx Distal Femur Spanning Attachment Plates (when used with either 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plate or the Proximal Femur Hook Plate) can be used to extend the length of a plate construct to the lateral condyles.

DePuy Synthes 3.5 mm VA Locking PPFX Greater Trochanter Ring Attachment Plates (when used with 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plate) are indicated for fixation or re-attachment of the greater trochanter following fracture or osteotomy.

DePuy Synthes 3.5 mm VA Locking PPFX Greater Trochanter Hook Plates are indicated for fixation or re-attachment of the greater trochanter following fracture or osteotomy.

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 - K210205

Sponsor	DePuy Synthes Satapa Dhamankar 1301 Goshen Parkway West Chester, PA 19380 Phone: +1 610 719 6574
Date prepared	March 23, 2021
Proprietary name	DePuy Synthes 3.5/4.5 mm Variable Angle LCP Periprosthetic Proximal Femur 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 Common Name: Plate, Fixation, Bone
Predicate device	Primary predicate: • Synthes Locking Attachment Plate (K083573) Additional/Reference predicates: • Synthes LCP Straight and Curved Plates (K041911, K082807, K092609, K000682) • 4.5 mm LCP Proximal Femur Hook Plate (K032032) • Trochanteric Reattachment Device (K001709)
Device description	The DePuy Synthes 3.5/4.5 mm Variable Angle LCP Periprosthetic Proximal Femur Plating System of Stainless Steel Plates for periprosthetic fractures. It consists of plates that offer screw to plate non-locking constructs, locking constructs or a combination of both. The plates accept commercially available DePuy Synthes Stainless Steel 3.5 mm cortex screws, 3.5 mm (variable angle) locking screws, 4.5 mm cortex screws and 5.0 mm (variable angle) locking screws, as well as the Synthes Orthopaedic Cable system. The DePuy Synthes 3.5/4.5 mm Variable Angle LCP Periprosthetic Proximal Femur Plating System offers: • 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plates • 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Hook Plates • 3.5 mm VA Locking PPFx Distal Femur Spanning Attachment Plate • 3.5 mm VA Locking PPFx Greater Trochanter Hook Plate • 3.5 mm VA Locking PPFx Greater Trochanter Ring Attachment Plate • 3.5 mm VA Locking Attachment Plate

Indications for use	DePuy Synthes 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plates and Proximal Femur Hook Plates are indicated for the treatment of periprosthetic fractures and fractures in the presence of intramedullary implants in the proximal end segment and the proximal and middle 1/3 of the diaphyseal segment of the femur, and non-unions or malunions of such fractures, in adult patients, particularly in osteoporotic and osteopenic bone. DePuy Synthes 3.5 mm VA Locking Attachment Plate is indicated to augment the stabilization of fractures, including periprosthetic fractures (Vancouver Type B when used with either the 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plate or Proximal Femur Hook Plate; Vancouver Type B and C when used with other DePuy Synthes LCP plates and VA-LCP plates) and fractures in the presence of intramedullary implants, in the femur, tibia, and humerus. DePuy Synthes 3.5 mm VA Locking PPFx Distal Femur Spanning Attachment Plates (when used with either the 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plate or the Proximal Femur Hook Plate) can be used to extend the length of a plate construct to the lateral condyles. DePuy Synthes 3.5 mm VA Locking PPFX Greater Trochanter Ring Attachment Plates (when used with the 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plate) are indicated for fixation or re-attachment of the greater trochanter following fracture or osteotomy. DePuy Synthes 3.5 mm VA Locking PPFX Greater Trochanter Hook Plates are indicated for fixation or re-attachment of the greater trochanter following fracture or osteotomy.
Contraindications	The DePuy Synthes 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plating System is contraindicated if the hip stem is loose, which requires immediate revision. The DePuy Synthes 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Plate with 2-holes (shortest plate) is contraindicated for diaphyseal periprosthetic femoral fractures where distal fixation of the construct is not achievable. The DePuy Synthes 3.5 mm/4.5 mm VA-LCP PPFx Proximal Femur Hook Plate with 5 holes (shortest plate) is contraindicated for diaphyseal periprosthetic femoral fractures where distal fixation of the construct is not achievable. The DePuy Synthes 3.5 mm VA Locking PPFx Distal Femur Spanning Attachment Plates are contraindicated for spanning a fracture.

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 of similar design intended for bone fracture fixation. Both subject and predicate devices are anatomically contoured plates. Both subject and predicate devices have similar hole specifications and are compatible with the same screw types. Both subject and predicate devices have similar connection mechanisms for the attachment of modular plates. Both subject and predicate devices are compatible with the Orthopaedic Cable System (K992616). The subject devices present the following features that are not found in the predicate device: • Subject devices incorporate well known and commercially available variable angle screw technology vs. the predicate devices which utilize standard locking screws • The subject system is a modular system, where multiple devices can be used in combination with each other to address a variety of surgeon / patient needs. • Subject devices offer a higher density of variable angle locking screw holes for additional fixation points The subject devices are made from Stainless Steel (316L), and the predicate device is made from Stainless Steel (316L), Commercially Pure Titanium (CPTi4) or Titanium Alloy (TAN). It can be concluded that the 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	The following performance data were provided in support of the substantial equivalence Mechanical testing of a broad range of possible constructs (plates with screws) under static and dynamic loading conditions have been performed to compare the proposed DePuy Synthes 3.5/4.5 mm Variable Angle LCP Periprosthetic Proximal Femur Plating System to the predicate device. The standards used to develop and perform mechanical testing are ASTM F382:2017, ASTM STP 731:1981 and ISO 12107-2nd Ed. The results of this testing support that the mechanical performance of the subject devices is 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

	3.5/4.5 mm Variable Angle LCP Periprosthetic Proximal Femur Plating System. The standards used to develop and perform Magnetic Resonance compatibility testing are ASTM F2052:2015, ASTM F2119:07(2013), ASTM F2182:19e2, ASTM F2213:2017 and ASTM F2503:2013 The devices in DePuy Synthes 3.5/4.5 mm Variable Angle LCP Periprosthetic Proximal Femur Plating System are provided both sterile and non-sterile. The validations for sterile devices are performed in accordance with ANSI/AAMI/ISO 11137:2015 demonstrating a Sterility Assurance Level (SAL) of 10^{-6} when sterilized utilizing gamma radiation. The sterile packaging shelf life of the DePuy Synthes Periprosthetic Proximal Femur Plating implants has been validated to be ten years when tested in accordance with ISO 11607-1:2020 “Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems” and ISO 11607-2:2020 “Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes.” Biological safety evaluation for the devices in DePuy Synthes 3.5/4.5 mm Variable Angle LCP Periprosthetic Proximal Femur Plating System was performed in accordance with ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process” and FDA guidance ‘Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"’ Endotoxin testing has been performed using the LAL test method to establish that the subject DePuy Synthes 3.5/4.5 mm Variable Angle LCP Periprosthetic Proximal Femur Plating System meets the specified endotoxin requirement of 20 EU/device. The standard used for Bacterial endotoxins testing is ANSI/AAMI ST72:2019
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.