June 2, 2021

DePuy Synthes
Ann-Christin Ponick
Senior Regulatory Affairs Specialist
Luzernstrasse 21
Zuchwil, Solotburn 4528
Switzerland

Re: K211051
Trade/Device Name: DePuy Synthes 2.7mm Straight and 2.7mm Adaption Plates (Modular Mini Fragment LCP 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: April 1, 2021
Received: April 8, 2021

Dear Ann-Christin Ponick:

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)*
K211051

Device Name
DePuy Synthes 2.7 mm LCP Plates (Modular Mini Fragment LCP System)

Indications for Use *(Describe)*
The DePuy Synthes 2.7 mm LCP Plates (Modular Mini Fragment LCP System) is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle.

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

Sponsor	DePuy Synthes 1301 Goshen Parkway West Chester, PA, 19380 **Primary Contact:** Ann-Christin Ponick Senior Regulatory Affairs Specialist DePuy Synthes Luzernstrasse 21 4528 Zuchil, Switzerland Phone: +41 79 585- 1916 E-Mail: aponick@its.jnj.com **Alternate Contact:** Stacey Bonnell Director, Regulatory Affairs DePuy Synthes 1301 Goshen Parkway West Chester, PA, 19380 Phone: (484) 238–7519 E-Mail: sbonnell@its.jnj.com
Date Prepared	May 26, 2021
Proprietary Name	DePuy Synthes 2.7 mm LCP Plates (Modular Mini Fragment LCP 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 (USA) Modular Mini Fragment LCP System (K063049)
Reference Device A	Stryker VariAx 2 Distal Radius Plating System (K141430)
Reference Device B	Stryker VariAx 2 Compression Plating System (K170727)
Device Description	The Synthes Modular Mini Fragment LCP (Locking Compression Plate) System consists of metallic plates and screws that merge locking screw technology with conventional plating techniques. Locking screws provide the ability to create a fixed-angle construct while utilizing familiar AO plating techniques. A fixed-angle construct provides improved fixation in osteopenic bone or multifragment fractures where traditional screw purchase is compromised.

	The subject plates are available in various sizes in sterile configurations and are available in stainless steel and commercially pure titanium. The system also consists of implantable screws (K112583) that correspond to the subject device.
Indications for use	The DePuy Synthes 2.7 mm LCP Plates (Modular Mini Fragment LCP System) is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle.
Non-clinical Performance Data	The non-clinical performance evaluation of the DePuy Synthes, 2.7mm LCP Plates per this submission has been compared to the existing DePuy Synthes, 2.7mm LCP plates with regards to mechanical performance. The evaluation supports that the mechanical performance of the subject devices are at least equivalent to that of the predicate devices. Magnetic Resonance compatibility evaluation has been performed to establish the MR Conditional parameters for the subject DePuy Synthes, 2.7mm LCP Plates. Endotoxin testing has been performed using to the LAL test method to establish that the subject DePuy Synthes 2.7mm LCP 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 LCP Plates are biologically safe when used as intended.
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The subject devices fully align with the indications for use compared to the predicate, Synthes (USA) Modular Mini Fragment LCP System (K063049). A comparison of the subject devices *DePuy Synthes 2.7mm Straight and 2.7mm Adaption Plates (Modular Mini Fragment LCP System)* demonstrated that they are substantially equivalent to the previously cleared Synthes (USA) Modular Mini Fragment LCP System (K063049), VariAx 2 Distal Radius Plating System (K141430) and the VariAx 2 Compression Plating System (K170727) from Stryker in regards to intended use, material, design, and operational principles. 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 questions of safety and effectiveness. It is concluded that the information provided herein supports substantial equivalence of the subject devices.