Synthes (USA) Products LLC
Thomas Shea
Manager, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

November 7, 2019

Re: K192327
Trade/Device Name: DePuy Synthes 2.4mm LCP Straight Wrist Plate, Sterile
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: October 7, 2019
Received: October 8, 2019

Dear Thomas Shea:

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)*
K192327

Device Name
DePuy Synthes 2.4mm LCP Straight Wrist Plate

Indications for Use *(Describe)*
The DePuy Synthes 2.4mm LCP Straight Wrist Plate is intended for Colles' and distal radius fractures with dorsal angulation of the distal fragment.

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 Thomas Shea 1301 Goshen Parkway West Chester, PA USA Phone: 610-719-5679
Date Prepared	August 22, 2019
Proprietary Name	DePuy Synthes 2.4mm LCP Straight Wrist Plate
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 2.4mm LCP Wrist Plate (K040588)
Reason for Submission	To introduce a sterile packaged version of the 2.4mm LCP Straight Wrist Plate.
Device Description	The 2.4mm LCP Straight Wrist Plate is designed for distal radius fractures with severe comminution requiring prolonged fixation, as an alternative to external fixation. Applied to the dorsal aspect of the wrist, the plate restores length and neutralizes loads on the consolidating fracture fragments.
Indications for use	The DePuy Synthes 2.4mm LCP Straight Wrist Plate is intended for Colles' and distal radius fractures with dorsal angulation of the distal fragment.
Contraindications	N/A
Comparison to Predicate	The subject device has the same indications for use, design, dimensions and material of manufacture as the predicate device.
Non-clinical Performance Testing	Verification activities support that the introduction of a sterile packaged version of the 2.4mm LCP Straight Wrist Plate will not affect the safety or performance.
Clinical Performance Data	Clinical data was not necessary for the determination of substantial equivalence.

Substantial Equivalence	The subject device has the same indications for use, design, dimensions and material of manufacture as the predicate device. The summary of verification and validation activities included in this submission supports that the addition of a sterile version of the 2.4mm LCP Straight Wrist Plate does not raise any issues regarding safety and effectiveness. It is concluded that the information provided in this submission supports substantial equivalence.