DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 9, 2017

DePuy Synthes
Joanna Rieder
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K163046
Trade/Device Name: DePuy Synthes 2.4/2.7mm Va Lcp Two-column Volar Distal Radius Plate, Extra-long
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 10, 2017
Received: January 11, 2017

Dear Joanna Rieder:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163046

Device Name

DePuy Synthes 2.4/2.7 mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long

Indications for Use *(Describe)*

INDICATIONS

The DePuy Synthes 2.4/2.7 mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long is intended for intra- and extra-articular fractures, osteotomies, nonunions and malunions of the distal radius, with or without extension into the radial diaphysis in adults and adolescents (12-21) where the growth plates have fused or will not be crossed, and the following adolescent distal radius fractures:

- Intra-articular fractures exiting the epiphysis
- Intra-articular fractures exiting the metaphysis
- Physeal crush injuries
- Any injuries which cause growth arrest to the distal radius.

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

Date Prepared: February 9, 2017

Sponsor:	DePuy Synthes Joanna Rieder 1301 Goshen Parkway West Chester, PA 19380 Office: +41 32 720 41 17 Fax +41 32 720 71 73
Proprietary Name:	DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long
Classification:	Classification: Class II Regulation Number: 21 CRF §888.3030 Product Code: HRS
Predicate Device	2.4MM VA-LCP DORSAL DISTAL RADIUS PLATES (K102694)
Reference Predicate	SYNTHES (USA) MODULAR MINI FRAGMENT LCP SYSTEM (K063049)

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Device Description:	The DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long will be available in stainless steel and titanium. The head of the plate will remain the same as the existing 2.4mm VA-LCP Two-Column Volar Distal Radius Plate (K102694) and will therefore allow the use of the existing guide block for these plates. The DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long will come in 3 different lengths (7 shaft holes, 10 shaft holes and 13 shaft holes). To accommodate different patient anatomy, the plate with 7 shaft holes will be available with three different plate head widths (Standard, Narrow and Wide). The 10 shaft hole and the 13 shaft hole plate will only be released with the Standard plate head width and additionally they feature a curvature in the shaft. All plates will feature left- and right-specific designs and will be offered in sterile packed only. The DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plates, Extra-Long are designed to accept existing 2.4mm Variable Angle Locking Screws, 2.4mm Cortex Screws, 2.4mm Locking Screws, 1.8mm VA Buttress Pins and 1.8mm Locking Buttress Pins in the plate head holes. In the plate shaft, existing 2.4mm Cortex Screws, 2.7mm Cortex Screws, 2.4mm Variable Angle Locking Screws, 2.7mm Variable Angle Locking Screws, 2.4mm Locking Screws, and 2.7mm Locking Screws can be inserted.
Indications for Use:	The DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long is intended for intra- and extra-articular fractures, osteotomies, nonunions and malunions of the distal radius, with or without extension into the radial diaphysis in adults and adolescents (12-21) where the growth plates have fused or will not be crossed, such as: - Intra-articular fractures exiting the epiphysis - Intra-articular fractures exiting the metaphysis - Physeal crush injuries - Any injuries which cause growth arrest to the distal radius
Comparison to Predicate:	The proposed DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long has similar indications, in comparison to the predicate devices. The features of the subject device are substantially equivalent to the predicate devices based on the similarities in intended use and design, where the new device can additionally treat fractures with extension to the radial shaft. Mechanical testing demonstrates substantial equivalence of the subject device to the predicates devices in regards to mechanical strength. In addition the intended use, manufacturing methods, packaging, and sterilization of the predicates compared to the subject devices are identical. The subject device and predicate devices are made from stainless steel (316L) or commercially pure titanium (CP4).

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Substantial Equivalence:	Functional and mechanical testing demonstrate that the proposed DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long is comparable in mechanical and functional properties to the predicate devices. Worst case plates were tested to assess the mechanical performance of the newly developed implants. The defined worst cases were tested under static and dynamic loading conditions and were then compared to the predicate devices: Four Point Bending Test was performed to access the mean static and median fatigue strength for non-contoured and contoured subject plates and evaluate the plate shaft performance. The new plates performed better than the predicate device. Construct (plate with screws) axial bending was performed to access the plate construct strength and evaluate the plate head performance. The new plates performed better than the predicate device. Torque Through Testing was performed to assess the mechanical properties of the plate to screw interface. Biocompatibility testing was performed to demonstrate that the DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long is biocompatible. LAL testing has been performed to establish that the subject device meets the specified 20EU/device limit. Based on the aforementioned mechanical testing, the subject DePuy Synthes 2.4/2.7mm VA-LCP Two-Column Volar Distal Radius Plate, Extra-Long is substantially equivalent to the predicate device.