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

March 29, 2017

DePuy Synthes
Christopher J. Medberry, PhD, RAC
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K162124
Trade/Device Name: Synthes 4.5mm VA-LCP Curved Condylar Plate System Line Extension, Variable Angle Positioning Pins
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDP, HWC, JDQ, HRS
Dated: March 1, 2017
Received: March 2, 2017

Dear Dr. Medberry:

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)*
K162124

Device Name
Synthes 4.5mm VA-LCP Curved Condylar Plate System Line Extension

Indications for Use *(Describe)*
The Synthes 4.5mm VA LCP Curved Condylar Plate System is indicated for buttressing multifragmentary distal femur fractures including: supra-condylar; intra-articular and extra-articular condylar fractures, periprosthetic fractures, fractures in normal or osteopenic bone, nonunions and malunions.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
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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)*
K162124

Device Name
Variable Angle Positioning Pins

Indications for Use *(Describe)*
The DePuy Synthes Variable Angle Positioning Pins are intended for use with cerclage multifilament cable to augment fracture stabilization with plates used in long bone fixation, when screw placement would be inhibited, as in the presence of intramedullary implant.

The Variable Angle Positioning Pins are designed for use with Variable Angle LCP plate implants featuring variable angle locking holes that accept 5.0 mm variable angle bone screws.

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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Date Prepared: March 28, 2017

Sponsor: DePuy Synthes

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Bundled Submission/Device Names:

1. Synthes 4.5mm VA-LCP Curved Condylar Plate System Line Extension
2. Variable Angle Positioning Pins

Regulation:

Screws*:* §888.3030; Condylar Plate Fixation Implant - Single/multiple component metallic bone fixation appliances and accessories

§888.3040; Screw, Fixation, Bone - Smooth or threaded metallic bone fixation fastener.

Positioning Pins: §888.3010; Cerclage, Fixation - Bone fixation cerclage.
System-specific Instruments: §888.3030; Condylar Plate Fixation Implant - Single/multiple component metallic bone fixation appliances and accessories;

Classification/ Product Code:

Screws: Class II / JDP, HWC
Positioning Pins: Class II /JDQ
System-specific Instruments: Class II / JDP, HRS, HWC

Predicate Devices: Synthes 4.5mm VA LCP Curved Condylar Plate System (K110354)
3.5 mm VA Locking Positioning Pin (K120689)

Reference Devices: Synthes 4.5 mm LCP Plate (K041911)
Synthes 4.5 mm Broad LCP Plate (K000682)
Synthes Cortical Screws (K112583)
LCP Condylar Plate (K000066)

Device Description: The Synthes 4.5mm VA-LCP Curved Condylar Plate System consists of anatomically-contoured, stainless steel and titanium plates and screws featuring variable angle locking and combi-holes designed to provide stable fixation of the distal femur and system-specific instrumentation. The current 510(k) introduces OPTILINK™ Technology stainless steel

screws, positioning pins for cerclage cable, and system-specific instrumentation as a line extension to the currently cleared Synthes 4.5mm VA-LCP Curved Condylar Plate System.

Intended Use/ Indications for Use:

Bundled Device #1 IFU:

Synthes 4.5mm VA-LCP Curved Condylar Plate System Line Extension

The Synthes 4.5mm VA-LCP Curved Condylar Plate System is indicated for buttressing multifragmentary distal femur fractures including: supra-condylar; intra-articular and extra-articular condylar fractures, periprosthetic fractures, fractures in normal or osteopenic bone, nonunions and malunions.

Bundled Device #2 IFU:

Variable Angle Positioning Pins

The DePuy Synthes Variable Angle Positioning Pins are intended for use with cerclage multifilament cable to augment fracture stabilization with plates used in long bone fixation, when screw placement would be inhibited, as in the presence of intramedullary implant.

The Variable Angle Positioning Pins are designed for use with Variable Angle LCP plate implants featuring variable angle locking holes that accept 5.0 mm variable angle bone screws.

Non-clinical Performance Data: Information presented supports substantial equivalence of the Synthes 4.5mm VA-LCP Curved Condylar Plate System Line extension parts and variable angle positioning pins compared to and compatible to the predicate Synthes 4.5mm VA-LCP Curved Condylar Plate System. The subject OPTILINK™ screws and Variable Angle Positioning Pins have the same indications for use, are similar in design, material, and fundamental technology as the predicates. The mechanical performance of the subject OPTILINK™ screws have been evaluated via Dynamic Fatigue Construct testing, Connection Strength testing, Torque-through and screw recess torsion tests, ASTM-543-13 Standard Specification and Test Methods for Metallic Medical Bone Screws testing, which evaluated Torsional Properties, Insertion/Removal Torque, and Pull-out Strength. The devices also meet the specified endotoxin requirement of 20EU/device using the LAL test method.

Clinical Performance Data:

Clinical data was not needed to demonstrate the safety and effectiveness of the proposed devices.

Material Characterization Evidence: The proposed OPTILINK™ technology screws have been evaluated to determine the metallurgical corrosion behavior via anodic polarization,

galvanic and fretting corrosion assessments using both stainless steel and titanium plates. Conclusions drawn from these evaluations demonstrate substantial equivalence to the predicate device.

Conclusion: The subject devices demonstrate substantial equivalence to the predicate devices.