September 20, 2022

DePuy Synthes
Alyssa Bryan
Regulatory Affairs Specialist I
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K221809
Trade/Device Name: DePuy Synthes 3.5mm Intrapelvic Acetabular 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: June 21, 2022
Received: June 22, 2022

Dear Alyssa Bryan:

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, MPH
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)*
K221809

Device Name
DePuy Synthes 3.5 mm Intrapelvic Acetabular System

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm Intrapelvic Acetabular Plates are indicated for fractures of the acetabulum in adults and adolescents (greather than 12 through 21 years of age) where all growth plates within the acetabulum are fused.

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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K221809 - 510(k) Summary

Sponsor	DePuy Synthes Alyssa Bryan 1301 Goshen Parkway West Chester, PA 19380 Phone: +41 61 965 63 14
Date Prepared	August 18, 2022
Proprietary Name	DePuy Synthes 3.5 mm Intrapelvic Acetabular 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 devices	Primary Predicate: Synthes (USA) Low Profile Reconstruction Plates K042377 • 3.5 mm Wide Angle Low Profile Reconstruction Plates • 3.5 mm Low Profile Reconstruction J-Plates (non-locking) Additional Predicate: Synthes 3.5 mm Low Profile Pelvic Reconstruction Plate K031573 • 3.5 mm Low Profile Reconstruction Plates • 3.5 mm Low Profile Curved Reconstruction Plates (radius 108 mm) • 3.5 mm Low Profile Curved Reconstruction Plates (radius 88 mm)
Device Description	The DePuy Synthes 3.5 mm Intrapelvic Acetabular System can be used to treat fractures of the acetabulum involving the anterior column, with or without involvement of the posterior column, including the quadrilateral surface (QS). The subject system is comprised of four plate types per anatomic side, left and right, (Large Extended, Small Extended, Large Standard and Small Standard) which are designed to accept the following existing cortex screws: 3.5 mm Cortex Screws, 3.5 mm Pelvic Cortex Screws, 3.5 mm Cortex Screws with low-profile head, 3.5 mm Stardrive Cortex Screws, and 4.5 mm Cortex Screws. The implants are available in a sterile configuration and are offered in Stainless Steel (SSt). In total the system is comprised of eight different plate designs. Each plate configuration consists of a long, slender suprapectineal portion that is intended to be placed along the anterior column, superior to the pelvic brim and a trapezoidal quadrilateral surface portion that is intended to be placed against the medial aspect of the posterior column, overlapping at least a portion of the quadrilateral surface. The suprapectineal portion is divided into anterior and posterior segments that are configured to mimic existing 3.5 mm reconstruction plates and a central segment, to which the quadrilateral surface portion is connected by two connecting bars.
Indications for use	The DePuy Synthes 3.5 mm Intrapelvic Acetabular Plates are indicated for fractures of the acetabulum in adults and adolescents (greater than 12 through 21 years of age) where all growth plates within the acetabulum are fused.

Contraindications	Not intended for patients with active growth plates.
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. Additional features are found in the subject Acetabular Plates that are not found in the predicate Low Profile Reconstruction Plates. However, these features do not alter the fundamental technology of the device and therefore do not raise new issues of safety and effectiveness: • Trapezoidal quadrilateral surface portion that is intended to be placed against the medial aspect of the posterior column overlapping at least a portion of the quadrilateral surface • Non-locking screw holes on the quadrilateral surface portion designed to target bone in the sciatic buttress • A non-locking oblique screw hole in the distal portion of the quadrilateral surface designed to target screw anchorage within the ischium while avoiding the acetabulum • Additional holes to facilitate plate placement with instrumentation as well as in-situ and ex-situ contouring The subject and predicate devices are both made from Stainless Steel (316L). 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	Mechanical testing of a worst-case construct under static and dynamic physiologic loading conditions have been performed to compare the proposed DePuy Synthes 3.5 mm Acetabular Plates to the predicate device. The results of this testing support that the mechanical performance of the subject device 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 mm Intrapelvic Acetabular System. Endotoxin testing has been performed using the LAL test method to establish that the subject DePuy Synthes 3.5 mm Acetabular System meets the specified endotoxin requirement of 20 EU/device.
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 issues related to mechanical performance, safety or efficacy and can be labeled MR Conditional. The proposed devices are at least as safe and effective as the predicate devices It is concluded that the information provided herein supports substantial equivalence of the subject devices.