Synthes (USA) Products, LLC
Suchitra Basu
Global Strategy Manager, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

July 24, 2018

Re: K180544
Trade/Device Name: DePuy Synthes Static Staples
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: June 22, 2018
Received: June 25, 2018

Dear Suchitra Basu:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180544

Device Name
DePuy Synthes Static Staples

Indications for Use *(Describe)*
The DePuy Synthes Static Staples are indicated for extra-articular closing-wedge osteotomies of the 1st ray of the forefoot.

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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DePuy Synthes

510(k) Summary

Date Prepared: July 23, 2018

Sponsor	DePuy Synthes Suchitra Basu, PhD, RAC 1301 Goshen Parkway West Chester, PA 19380 Phone: +1-610-719-5448
Date Prepared	July 23, 2018
Proprietary Name	DePuy Synthes Static Staples
Common or Usual Name(s)	Bone Staple, Staple, Accessories
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Classification	Class II Regulation Number: 21 CFR 888.3030 Product Code: JDR
Predicate Devices	Primary Predicate: Zimmer Biomet Varisation Staple (K931155) Additional Predicates: Trilliant Surgical Sniper Staple System (K162354), EPIC Extremity Small Staple (K163226)
Reference Device	Synthes (USA) 1.5mm Mini Fragment LCP System (K090047)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the DePuy Synthes Static Staples.

Device Description	The DePuy Synthes Static Staple is an implant for bone fixation designed for extra-articular closing wedge osteotomies of the 1st ray of the forefoot. The implant is offered in two (2) configurations of 26° and 90° to address varying patient anatomy of the foot, particularly the 1st ray of the forefoot. The Static Staple implant is delivered to the operating room in a disposable, sterile kit, preloaded onto a handheld inserter along with drill guide and K-wires.
Indications for use	The DePuy Synthes Static Staples are indicated for extra-articular closing wedge osteotomies of the 1st ray of the forefoot.

DePuy Synthes

Non-clinical Performance Data	The following analysis were conducted: • Static Bend according to ASTM F564 • Dynamic bending according to ASTM F564 • Pull-out testing according to ASTM F564 • MRI Conditional Testing to establish MR Conditional parameters
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence	The Static Staples implants possess the equivalent technological characteristics as that of the primary predicate devices (K931155). These include: • performance, • basic design, • material and • sizes (dimensions are comparable to those offered by the predicate systems). The proposed device has indications for use which are fully encompassed by the indications for use of the predicate device. The mechanical testing and analytical evaluation included in this submission demonstrate that: • Any differences in technological characteristics of the subject devices do not raise any new questions of safety and effectiveness. • The proposed devices are at least as safe and effective as the predicate devices. Based on the indications for use, technological characteristics, and the summary of data submitted, it is concluded that the information provided in this submission supports substantial equivalence.