Synthes (USA) Products, LLC
Keith Knapp
RA Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

February 26, 2020

Re: K191463
Trade/Device Name: DePuy Synthes Hammertoe Continuous Compression Implant
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: January 24, 2020
Received: January 27, 2020

Dear Keith Knapp:

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 Vesa Vuniqi
Assistant Director
DHT6A: Division of Joint Arthroplasty 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)*
K191463

Device Name
DePuy Synthes Hammertoe Continuous Compression Implant

Indications for Use *(Describe)*
The DePuy Synthes Hammertoe Continuous Compression Implant is indicated for small bone reconstruction and fusion of the phalanges in the toes.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary

Sponsor	DePuy Synthes Keith Knapp 1301 Goshen Parkway West Chester, PA 19380 Phone: +1-610-719-5942
Date Prepared	February 2020
Proprietary Name	DePuy Synthes Hammertoe Continuous Compression Implant
Device Common Name	Staple, Fixation, Bone
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 Device: BioMedical Enterprises, Inc. OSStaple (K993714) Secondary Predicate Device: BioMedical Enterprises, Inc. Hammerlock 2(K133520)
Device Description	The implants of the DePuy Synthes Hammertoe Continuous Compression Implant System are made of biocompatible Nitinol and are designed to exhibit pseudoelastic (superelastic) properties at room temperature. Each implant is supplied pre-loaded on an insertion stick assembly in a constrained state, with the legs parallel. It is inserted into pre-drilled holes and released utilizing the insertion slider and if necessary, impaction on the proximal end of the insertion stick. Upon release, the implants attempt to return to their original unconstrained shape and thus provide compression to the bones across the osteotomy or arthrodesis site. The implants do not require any external heating; they are completely transformed at ambient temperature. In good bone quality, this deflection may not be visible as the legs are constrained by the surrounding tissue. The implant is offered in two (2) sizes to address varying patient anatomy of the foot.

	The implant is delivered to the operating room in a disposable, sterile kit, preloaded onto a handheld insertion stick assembly along with a drill pin, drill guide, locator pins and K-wires.
Indications for use	The DePuy Synthes Hammertoe Continuous Compression Implant is indicated for small bone reconstruction and fusion of the phalanges in the toes.
Comparison to Predicate	The design, features, and specifications of the subject and primary predicate systems compared below. The shared technological characteristics are as follows: • Range of staple legs of the subject device are within range of those offered in the predicate device. • The material of both the subject device and predicate device is Nitinol. Technical characteristics found in the subject implants that are not found in the primary predicate are listed below: • The predicate requires the application of an electrical current to the staple after implant placement to heat and transform the nitinol material, the subject device requires no additional steps after implant placement. The principles of operation – compression across the operative site – are the same in both devices. • The predicate has smooth legs while the subject device features three (3) barbs. This increases the pullout strength of the subject device compared to the predicate. The design, features, and specifications of the subject and secondary predicate systems compared below. The shared technological characteristics are as follows: • The material of both the subject device and predicate device is Nitinol. • Both devices include barbed legs for increased pullout strength • Both devices require no external energy source to achieve compression Technical characteristics found in the subject implants that are not found in the secondary predicate are listed below: • The predicate is inserted in an intramedullary fashion while the subject device in inserted extra-medullary, but both are intended to bridge the fusion site and provide compression. • The predicate includes a greater number of legs.

Non-clinical Performance Data	The following analysis were conducted: • Static Bend according to ASTM F564 • Pullout testing was performed according to ASTM F564 • Corrosion testing was performed according to ASTM F2129 • Dynamic Bend Testing • Endotoxin Testing was performed according to AAMI ST72 Other Additional Testing: • MRI Conditional analysis has been performed to establish MR Conditional parameters for the subject DePuy Synthes Hammertoe Continuous Compression Implant
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The DePuy Synthes Hammertoe Continuous Compression Implants possess the equivalent technological characteristics as that of the primary predicate device. These include: • principles of operation • basic design • material • sizes (dimensions are comparable to those offered by the predicate systems) The DePuy Synthes Hammertoe Continuous Compression Implants possess the equivalent technological characteristics as that of the secondary predicate device. These include: • material • method of compression • design features The proposed device has indications for use that are fully encompassed by the indications for use of the primary and secondary predicate device and both the subject and predicate devices are manufactured from the same nitinol material. 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 primary and secondary predicate devices. It is concluded that the information provided in this submission supports substantial equivalence.