Synthes (USA) LLC
Christopher Medberry
Project Leader, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

December 21, 2018

Re: K180821
Trade/Device Name: TruMatch Graft Cage - Long Bone
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: November 26, 2018
Received: November 26, 2018

Dear Christopher 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Daniel S. Ramsey -S
2018.12.21 15:27:52 -05'00'

FOR 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)*
K180821

Device Name
TruMatch Graft Cage - Long Bone

Indications for Use *(Describe)*
The DePuy Synthes TruMatch Graft Cage – Long Bone implant is indicated for use in skeletally mature adults and adolescents (12-21)* for maintaining the relative position of bone grafts and/or bone graft substitutes within bone voids or surgical resections in the nonarticular regions of the humerus, femur, or tibia. The implant must be used in conjunction with traditional, rigid fixation.
*The TruMatch Graft Cage – Long Bone implant is indicated for use in skeletally immature adolescents, only if the device is not used across open physes.
The TruMatch Graft Cage – Long Bone implant is for patients only when the treating physician deems there is appropriate time to conduct surgical planning, personalization, and manufacturing of a patient specific device. When considering the use of the TruMatch Graft Cage - Long Bone, please ensure that you request information on the amount of time needed to manufacture and ship the device from your local DePuy Synthes sales representative. There is a delay between when the device is ordered and when the device can be delivered.

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.

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510(k) Summary	
Sponsor:	**Synthes (Usa) Products, Llc** **Primary Contact:** Christopher J. Medberry, PhD, RAC Project Leader, Regulatory Affairs DePuy Synthes 1301 Goshen Parkway West Chester, PA 19380 Phone: (610) 719- 6806 cmedberr@its.jnj.com **Alternate Contact:** Stacey Bonnell, MBA, RAC Associate Director, Regulatory Affairs DePuy Synthes 1301 Goshen Parkway West Chester, PA 19380 Phone: mobile (484) 238-7519 sbonnell@its.jnj.com
Date Prepared:	December 20th, 2018
Proprietary Name:	TruMatch Graft Cage – Long Bone
Classification:	Classification: 888.3030 – Bone Fixation Appliances & Accessories Product Code: HRS – Plate Fixation Bone
Predicate Device:	OrthoMesh (K073115)
Reference Device:	TRS Cranial Bone Void Filler (K123633)
Device Description:	DePuy Synthes TruMatch Graft Cage - Long Bone, is a 3D-printed personalized resorbable implant that optimizes support of bone graft in large, segmental defects of the humerus, femur, and tibia.
Indications for Use:	The DePuy Synthes TruMatch Graft Cage – Long Bone implant is indicated for use in skeletally mature adults and adolescents (12-21)* for maintaining the relative position of bone grafts and/or bone graft substitutes within bone voids or surgical resections in the nonarticular regions of the humerus, femur, or tibia. The implant must be used in conjunction with traditional, rigid fixation. *The TruMatch Graft Cage – Long Bone implant is indicated for use in skeletally immature adolescents, only if the device is not used across open physes. The TruMatch Graft Cage – Long Bone implant is for patients only when the treating physician deems there is appropriate time to conduct surgical planning, personalization, and manufacturing of a patient specific device. When considering the use of the TruMatch Graft Cage - Long Bone, please ensure that you request information on the amount of time needed to

510(k) Summary	
	manufacture and ship the device from your local DePuy Synthes sales representative. There is a delay between when the device is ordered and when the device can be delivered.
Intended use:	Bone graft/bone graft substitute support and containment
Substantial Equivalence:	The subject device, TruMatch Graft Cage – Long Bone, has substantially equivalent indications, technological characteristics, materials, and performance as compared to the predicate and reference devices. The present submission compared the subject device to the primary predicate, OrthoMesh (K073115), and reference device, TRS Cranial Bone Void Filler (K123633). *Summary Comparison of Indications* The subject device has highly similar indications to a subset of that of the predicate device, wherein both devices are intended to provide support and containment to bone graft/ bone graft substitute and can only be used in combination with a rigid fixation device. The predicate device also has indications to be used without a rigid fixation device in certain anatomic locations, which are not indicated for the subject device. The comparison of indications supports substantial equivalence. *Summary Comparison of Technological Characteristics* The subject device, TruMatch Graft Cage – Long Bone, and predicate device, OrthoMesh, are both intended to provide support and containment to bone graft/ bone graft substitute. The devices have highly similar technological characteristics, with differences that do not affect the ability of the devices to perform their intended use. Both devices are composed of resorbable polymers with resorption rates that enable support and containment to be provided over the course of bone healing. The subject device is composed of 96% polycaprolactone/ 4% hydroxyapatite and has an approximate degradation rate of 2-4 years as supported by literature, while the predicate device is composed of 85:15 poly (L-lactide-co-glycolide) and has a degradation rate of approximately 1 year. The degradation rate of the subject device is comparable to that of the reference device (TRS Cranial Bone Void Filler) as they are composed of the same material, same coating, manufactured using the same additive manufacturing methods, and sterilized using ethylene oxide. Both the subject and predicate devices are designed to be patient matching. While the subject device is manufactured to fit a patient specific geometry, the predicate device is shaped to match a patient's bone within the operating room. Though the geometrical structure of the devices differ, both the subject and predicate devices have an outer structure to provide support laterally. The subject device also provides support bone graft/bone graft substitute with an inner structure.

510(k) Summary	
	The comparison of technological characteristics supports substantial equivalence. *Summary Comparison of Performance Testing* The performance of the subject device TruMatch Graft Cage – Long Bone was demonstrated to be substantially equivalent to predicate device OrthoMesh using an axial compression biomechanical test and a pre-clinical animal model. Axial compression testing demonstrated increased elastic deformation of the subject device as compared to the predicate device. The pre-clinical testing utilized an ovine model of a large bone defect and demonstrated that the subject device was substantially equivalent to the predicate device in terms of radiographic union, torsional testing, μCT analysis, histopathology, and histomorphometry. Additionally, testing was provided demonstrating that the subject device met endotoxin requirements (less than 20EU/device), had EO and ETO residuals less than the required amount per ISO 10993-7, was mechanically stable throughout the shelf life period, and can be accurately personalized and manufactured to meet patient specific geometries. The performance testing supports substantial equivalence. *Clinical data* Clinical data was not required to demonstrate the substantial equivalence of the subject device. *Conclusions* The conclusions drawn from the comparison of indications, technological characteristics, and performance testing demonstrate substantial equivalence of subject device TruMatch Graft Cage – Long Bone to the legally marketed predicate OrthoMesh (K073115).