DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 10, 2016

Synthes USA, LLC
Stacey Bonnell
Associate Director Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K161417
Trade/Device Name: DePuy Synthes MAXFRAME™ Multi-Axial Correction System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, OSN
Dated: May 20, 2016
Received: May 23, 2016

Dear Ms. Bonnell:

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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PART NUMBER	DESCRIPTION
03.312.813	MAXFRAME Strut Long, Quick Adjust
03.312.812	MAXFRAME Strut Medium, Quick Adjust
03.312.811	MAXFRAME Strut Short, Quick Adjust
03.312.810	MAXFRAME Strut X-Short, Quick Adjust
03.312.818	MAXFRAME Strut Long, Standard
03.312.817	MAXFRAME Strut Medium, Standard
03.312.816	MAXFRAME Strut Short, Standard
03.312.815	MAXFRAME Strut X-Short, Standard
03.312.814	MAXFRAME Strut XX-Short, Standard
03.312.090	MAXFRAME full ring 90mm, Aluminum
03.312.120	MAXFRAME full ring 120mm, Aluminum
03.312.150	MAXFRAME full ring 150mm, Aluminum
03.312.180	MAXFRAME full ring 180mm, Aluminum
03.312.210	MAXFRAME full ring 210mm, Aluminum
03.312.240	MAXFRAME full ring 240mm, Aluminum
03.312.270	MAXFRAME full ring 270mm, Aluminum
03.312.350	MAXFRAME Bridging Plate for 5/8 ring 150mm, Aluminum
03.312.380	MAXFRAME Bridging Plate for 5/8 ring 180mm, Aluminum
03.312.410	MAXFRAME Bridging Plate for 5/8 ring 210mm, Aluminum
03.312.440	MAXFRAME Bridging Plate for 5/8 ring 240mm, Aluminum
03.312.590	MAXFRAME 5/8 ring 90mm, Aluminum
03.312.620	MAXFRAME 5/8 ring 120mm, Aluminum
03.312.650	MAXFRAME 5/8 ring 150mm, Aluminum
03.312.680	MAXFRAME 5/8 ring 180mm, Aluminum
03.312.710	MAXFRAME 5/8 ring 210mm, Aluminum
03.312.740	MAXFRAME 5/8 ring 240mm, Aluminum
03.312.141	MAXFRAME Foot Plate short 140mm, Aluminum
03.312.161	MAXFRAME Foot Plate short 160mm, Aluminum
03.312.181	MAXFRAME Foot Plate short 180mm, Aluminum
03.312.201	MAXFRAME Foot Plate short 210mm, Aluminum
03.312.241	MAXFRAME Foot Plate long 140mm, Aluminum
03.312.261	MAXFRAME Foot Plate long 160mm, Aluminum
03.312.281	MAXFRAME Foot Plate long 180mm, Aluminum
03.312.301	MAXFRAME Foot Plate long 210mm, Aluminum
03.312.830	MAXFRAME Shoulder Bolt for 8mm Rings

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)*
K161417

Device Name
DePuy Synthes MAXFRAME™ Multi-Axial Correction System

Indications for Use *(Describe)*
The DePuy Synthes MAXFRAME™ Multi-Axial Correction System is indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which the growth plates have fused or will not be crossed with hardware:

- fracture fixation (open and closed)
- pseudoarthrosis of long bones
- limb lengthening (epiphyseal or metaphyseal distraction)
- joint arthrodesis
- infected fractures or nonunions
- correction of bony or soft tissue deformities
- correction of segmental defects.

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."

510(k) Summary

Date Prepared:	November 3, 2016
Submitter:	DePuy Synthes 1301 Goshen Parkway West Chester, PA 19380 - United States of America
Primary Contact:	Stacey Bonnell Associate Director, Regulatory Affairs – DePuy Synthes (610) 719-5895 sbonnell@its.jnj.com
DEVICE NAME	DePuy Synthes MAXFRAME™ Multi-Axial Correction System
Classification Name:	Single/multiple component metallic bone fixation appliances
Regulatory Class:	II
Product Code(s):	KTT (Appliance, fixation, nail/blade/plate combination, multiple components) OSN (Software for diagnosis/treatment)
PREDICATE DEVICE(S)	Smith & Nephew Circular Fixation System (rebranded as Taylor Spatial Frame or TSF) – K093047 Synthes Distraction Osteogenesis (DO) System – K092190
DEVICE DESCRIPTION	The DePuy Synthes MAXFRAME™ Multi-Axial Correction System, with adult and pediatric indications, is an external ring fixation system that is combined with web-based software in treatment of soft tissue and bone deformities. In the MAXFRAME system, implanted transfixion wires, Schanz screws and pins are attached to the rings and plates surrounding the deformity using bolts, nuts and connecting plates. Upper and lower rings are then connected to one another using six telescoping struts, creating a "Stewart Platform" type device. Adjusting the strut length allows for correction of length, rotation, and angular deformity at the same time. The modular nature of a ring fixation frame allows multiple frame options. A ring fixation frame is assembled individually by the surgeon to address the different characteristics of each case. The materials of construction for this system include aluminum, elgiloy, stainless steel and various polymeric materials. This system has been validated as MR Conditional.

INTENDED USE	The DePuy Synthes MAXFRAME™ Multi-Axial Correction System is intended for external fixation of fractured long bones and bones of the foot, limb lengthening, and deformity correction in adult, children* (3-12), and adolescent* (12-21) patient populations. The DePuy Synthes MAXFRAME™ Multi-Axial Correction System utilizes software for assisting surgeons in treatment planning. *in which the growth plates have fused or will not be crossed.
INDICATIONS FOR USE	The DePuy Synthes MAXFRAME™ Multi-Axial Correction System is indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which the growth plates have fused or will not be crossed with hardware: • fracture fixation (open and closed) • pseudoarthrosis of long bones • limb lengthening (epiphyseal or metaphyseal distraction) • joint arthrodesis • infected fractures or nonunions • correction of bony or soft tissue deformities • correction of segmental defects.
COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES	The DePuy Synthes MAXFRAME™ Multi-Axial Correction System has similar intended use, indications, design characteristics, functionality, materials, and performance characteristics in comparison to the predicate devices. The following assessments have been completed to demonstrate substantial equivalence performance specifications: • Construct testing (ASTM 1541-02 2011) and component testing including Static & Dynamic Compression testing, Static Torsion, Static Cantilever, Static and Dynamic Fatigue, Wire Slip and Ring to Wire Interface Testing • System Validation • Software Verification (in accordance with Special Controls & EN IEC 62304:2006-05 Medical device Software life cycle processes) • MR Conditional Technical Data (in accordance with FDA Guidance and ASTM F2503-13) • Reprocessing of SUD in accordance with Special Controls
CLINICAL EVAL	Clinical testing was not necessary for the determination of substantial equivalence.
CONCLUSION	The objective evidence presented demonstrates that the mechanical performance of the proposed device is comparable to that of the predicate device(s) and supports substantial equivalence for safety and effectiveness. The proposed device has a similar intended use, indications for use, and fundamental principles as the predicate devices.