May 25, 2021

Synthes (USA) Products, LLC
Suchitra Basu
Associate Director, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K211313
Trade/Device Name: MAXFRAME™ Multi-Axial Correction System (aka MAXFRAME)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: OSN, KTT
Dated: April 29, 2021
Received: April 30, 2021

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. 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,

Ting Song, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211313

Device Name
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.

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6 510(k) Summary

K211313

Sponsor	**Synthes**	**Address**
Primary Contact	Suchitra Basu, PhD, RAC Associate Director, Regulatory Affairs DePuy Synthes	1301 Goshen Parkway West Chester, PA USA T: 610-719-5448 Email: sbasu23@its.jnj.com
Secondary Contact	Thomas Shea Regulatory Affairs Manager DePuy Synthes	1301 Goshen Parkway West Chester, PA USA T: 610-719-5679 Email: tshea@its.jnj.com
Date Prepared	April 27, 2021	
Proprietary Name	MAXFRAME™ Multi-Axial Correction System (aka MAXFRAME)	
Device Name	MAXFRAME™ Multi-Axial Correction System (aka MAXFRAME)	
Common Name	Software for Diagnosis/Treatment; Single/multiple component metallic bone fixation appliances	
Classification	Class II Product Code(s): OSN (Software for Diagnosis/Treatment), KTT (Appliance, fixation, nail/blade/plate combination, multiple components)	
Predicate Device(s)	DePuy Synthes MAXFRAME™ Multi-Axial Correction System (K161417)	
Reference Device(s)	None	
Reason for Submission	To introduce MAXFRAME 3D II Software (software re-write of MaxFrame Web Software) compatible with existing MaxFrame Hardware cleared as a part of the MAXFRAME Multi Axial Correction System in K161417	
Device Description	The DePuy Synthes MAXFRAME™ Multi Axial Correction System, is an external ring fixation system that consists of MAXFRAME Hardware (schanz screws, pins, struts, rings) and MAXFRAME Web Software, used in treatment of soft tissue and bone deformities. The subject device MAXFRAME 3D II Software (Moderate Software Level of Concern) is a software re-write of the MAXFRAME Web Software to make it more efficient, simplify software upgrades for functionality and fixing of software anomalies or bugs. Additionally, based on surgeon feedbacks and voice of customer, new functionality has been added around how frames are identified on X-Rays/radiographic images and how the treatment of the deformity can be planned.	
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 to Predicate	The DePuy Synthes MAXFRAME 3D II Software has the same indications for use and design (fundamental software architecture) as the MAXFRAME Web Software. It utilizes the existing MAXFRAME hardware, creates a similar patient treatment plan, and has highly comparable functionality and usability to the predicate MAXFRAME Web Software.
Non-clinical Performance Testing	The performance of the subject MAXFRAME 3D II Software has been evaluated by confirming that the outputs meet the input requirements and conform to the user needs and intended uses.
Clinical Performance Data	Clinical data was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The subject device has the same intended use, indications for use, and fundamental principles as the predicate device. It has been adequately compared to the predicate device to demonstrate substantial equivalence
Conclusion	The results of non-clinical performance data in terms of software verification and validation demonstrate that the subject device is substantially equivalent to the predicate device.