July 26, 2023

Depuy Synthes
Mitchel Bartko
Regulatory Affairs Specialist III
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K231922
Trade/Device Name: DEPUY SYNTHES MAXFRAME AUTOSTRUT 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
Dated: June 29, 2023
Received: June 29, 2023

Dear Mitchel Bartko:

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,

Lixin Liu -S

Lixin Liu, Ph.D.
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)*
K231922

Device Name
DEPUY SYNTHES MAXFRAME AUTOSTRUT System

Indications for Use *(Describe)*
The MAXFRAME AUTOSTRUT System is indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which 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.

510(k) Summary

Sponsor	DePuy Synthes	Address
Primary Contact	Mitchel Bartko Regulatory Affairs Specialist III DePuy Synthes	1301 Goshen Parkway West Chester, PA USA T: 908-808-6541 Email: mbartko1@its.jnj.com
Secondary Contact	Silvia De La Barra Manager, Regulatory Affairs DePuy Synthes	1301 Goshen Parkway West Chester, PA USA T: 385-258-9397 Email: sdelabar@its.jnj.com
Date Prepared	June 29, 2023	
Device Trade Name	DEPUY SYNTHES MAXFRAME AUTOSTRUT System	
Common Name	External Fixation System	
Classification	Class II	
Product Code	KTT (Appliance, fixation, nail/blade/plate combination, multiple components)	
Regulation Number	888.3030 : Single/multiple component metallic bone fixation appliances and accessories	
Predicate Device(s)	K202810 – Autostrut G2	
Device Description Summary	The MAXFRAME AUTOSTRUT System is comprised of a control system, software, and six length-adjustable struts powered by a motor. The devices are used in conjunction with the DePuy Synthes MAXFRAME multi axial correction system (K161417), including all its parts and software, except that the MAXFRAME struts are substituted with the MAXFRAME AUTOSTRUT Hexapod Struts. This submission is solely for the clearance of a sterile version of the MAXFRAME AUTOSTRUT Hexapod Struts. The MAXFRAME AUTOSTRUT Hexapod Struts are provided sterile and are comprised of telescopic rods made of stainless steel and aluminum and a motor adapter made from polymeric material. The MAXFRAME AUTOSTRUT Hexapod Struts are available in three lengths - short, medium, and long. The MAXFRAME AUTOSTRUT Control System and Software have been cleared under K202810.	
Intended Use	The MAXFRAME AUTOSTRUT 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. *in which growth plates have fused or will not be crossed.	

Indications for Use	The MAXFRAME AUTOSTRUT System is indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which 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.
Indications for Use Comparison	The MAXFRAME AUTOSTRUT System has the same indications for use as the predicate device (AutoStrut G2 [K202810]).
Technological Comparison	The DePuy Synthes MAXFRAME AUTOSTRUT System has similar technological characteristics (design, material and chemical composition) as the predicate device AutoStrut G2 (K202810). The only differences between the predicate and subject device is that the subject device struts are provided ethylene oxide sterilized and packaged within sterile barrier packaging. The predicate device struts are provided non-sterile and are end user steam sterilized.
Non-clinical Performance Testing	Non-Clinical Performance Testing was performed and included Mechanical Testing, Shelf-Life Validation, Packaging Validation, Sterilization Validation and Biocompatibility Evaluation. The data was used for the determination of substantial equivalence.
Clinical Performance Data	Clinical Performance Data was not necessary for the determination of substantial equivalence.
Conclusion	These minor differences in the technological characteristics compared to the predicate do not raise different questions of safety or effectiveness. Bench testing demonstrates that the sterile MaxFrame AutoStrut Hexapod Strut is as safe and effective as its predicate device. Therefore, MaxFrame AutoStrut System is substantially equivalent to its predicate. The purpose of this 510(k) submission is to clear the sterile version of the MAXFRAME AUTOSTRUT Hexapod Strut only. The MAXFRAME AUTOSTRUT Control System and Software have been cleared under K202810.