August 14, 2019

OrthoSpin
% Janice Hogan
Partner
Hogan Lovells US LPP
1735 Market Street
Suite 2300
Philadelphia, Pennsylvania 19103

Re: K191241
Trade/Device Name: AutoStrut
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: July 12, 2019
Received: July 12, 2019

Dear Janice Hogan:

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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*

K191241

Device Name
AutoStrut

Indications for Use *(Describe)*

AutoStrut is indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which growth plates have fused and 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.

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510(k) SUMMARY

OrthoSpin's AutoStrut

OrthoSpin, Ltd.

17 Techelet Street,
Misgav, Israel
Phone: 972 722607075
Facsimile: +972.72.260.7222

Contact Person: Oren Cohen

Date Prepared: May 8, 2019

Name of Device: AutoStrut

Common or Usual Name: External ring fixation system

Classification Name: Single/ multiple component metallic bone fixation appliance

Predicate Devices

K161417 DePuy Synthes MAXFRAME multi axial correction system

Reference device:

K981423 Autogenesis Automator 2000

Intended Use / Indications for Use

AutoStrut is indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which growth plates have fused and 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.

Technological Characteristics

AutoStrut is comprised of six length-adjustable struts powered by a motor, a control system and software. The device is used in conjunction with the predicate DePuy Synthes MAXFRAME multi axial correction system (K161417), including all its parts and software but the MAXFRAME struts are substituted with the AutoStrut motorized struts.

The predicate MAXFRAME was cleared with software that generates a treatment plan for the patient, detailing how much each strut should be extended after a given amount of time. The output of this software is downloaded to the control box which will then automatically extend the motorized Autostruts the predetermined amount at the prespecified times.

The struts are supplied sterile via EtO.

Performance Data

- Sterilization validation per ISO 11135
- Cytotoxicity testing per ISO 10993-5
- Software characterization and validation
- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Static compression, static torsion, static cantilever bending, and dynamic compression/tension testing per ASTM F1541
- Extension speed and resolution testing

Substantial Equivalence

No changes, aside from replacing the struts, are being made to the predicate MAXFRAME components or its software. Similarly, the indications for the system are not being changed. Therefore, the substantial equivalence review is limited to the struts.

The most significant difference between the subject and predicate struts is that the predicate struts are adjusted manually, while the subject struts are automatically adjusted via motorized control. Motor controlled fixation systems have been previously cleared, such as the Autogenesis Automator (K981423) (reference device). Thus, replacing manual adjustment with a motorized adjustment does not raise different questions of safety or efficacy as the question remains if the clinically correct adjustment is received. As the motorized adjustment simply carries out the treatment plan generated by the same software as the predicate device, there is no change to the delivered treatment. The motorized struts of AutoStrut generate the same adjustment steps of a manual adjustment as per the MAXFRAME multi axial correction system treatment software.

Speed and accuracy tests of AutoStrut vs MAXFRAME have verified that the accuracy and speed of adjustment is similar or better than the MAXFRAME strut. The additional motors and components inside the struts add 540 gr weight to the entire fixation system. Construct testing per ASTM 1541 show that the AutoStrut performs at least as well as the MAXFRAME multi axial correction system.

Conclusions

The AutoStrut is substantially equivalent to its predicate.