January 6, 2021

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

Re: K202810
Trade/Device Name: AutoStrut G2
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: November 27, 2020
Received: November 27, 2020

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,

Ting Song, Ph.D., R.A.C.
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)*

K202810

Device Name

AutoStrut G2

Indications for Use *(Describe)*

AutoStrut G2 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.

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510(k) SUMMARY

OrthoSpin's AutoStrut G2

OrthoSpin, Ltd.

13 Hayezira Street,
Yokneam, Israel

Phone: +972.54.334.2651
Facsimile: +972.46886054

Contact Person: Oren Cohen

Date Prepared: January 5, 2021

Name of Device: AutoStrut G2

Common or Usual Name: External ring fixation system

Product Codes: KTT, OSN

Regulation Name: 21 CFR 888.3030 Single / multiple component metallic bone fixation appliances and accessories

Predicate Devices

K191241 AutoStrut, OrthoSpin Ltd.

Intended Use / Indications for Use

AutoStrut G2 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

The AutoStrut G2 is comprised of 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 AutoStrut G2 motorized struts.

The 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 AutoStrut G2 control box which will then automatically extend the motorized struts the predetermined amount at the prespecified times. The AutoStrut G2 struts are provided in three (3) sizes, Large, Medium and Small corresponding to the MAXFRAM and should be steam sterilized by the user prior to use.

Performance Data

• Static compression, static torsion, static cantilever bending, and dynamic compression/tension testing per ASTM F1541
• Electrical safety testing per IEC 60601-1 and IEC 60601-1-11
• EMC testing per IEC 60601-1-2
• Software characterization and validation
• Sterilization validation per ISO 17665-1, ISO 17665-2, ISO 11737-1 and ISO 11737-2
• Cytotoxicity testing per ISO 10993-5
• Speed and accuracy evaluation
• Reliability, force and accuracy test
• Corrosion Test

Substantial Equivalence

AutoStrut G2 is substantially equivalent to OrthoSpin's AutoStrut (K191241). AutoStrut G2 has the exact same indications as the AutoStrut (K191241). Furthermore, it has the same principles of operation and similar technological characteristics as the previously cleared predicate AutoStrut. The primary differences between AutoStrut G2 and AutoStrut are: the motors are assembled separately from the telescopic rods, control box modifications, addition of short strut length to existing medium and long lengths, and software modification to enable more increments per day of rod expansion. In addition, the sterilization method was changed from EtO to steam sterilization by the end user.

These minor differences in the technological characteristics compared to the predicate do not raise different questions of safety or efficacy. Bench testing demonstrates that the AutoStrut G2 is as safe and effective as its predicate device.

Conclusions

The AutoStrut G2 is substantially equivalent to its predicate.