December 10, 2020

Spinal Simplicity LLC
Mr. Adam Rogers
Director of Regulatory
6600 College Blvd, Suite 220
Overland Park, Kansas 66211

Re: K200066
Trade/Device Name: Posterior Fusion Plate, HA Posterior Fusion Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: November 18, 2020
Received: November 19, 2020

Dear Mr. Rogers:

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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200066

Device Name
Spinal Simplicity Posterior Fusion Plate

Indications for Use *(Describe)*
The Spinal Simplicity Posterior Fusion Plate is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation); and/or
- tumor.

The Posterior Fusion Plate is intended for use with bone graft material and is not intended for standalone use. The device may be implanted via a minimally invasive posterior approach (T1-S1) or a minimally invasive lateral approach (L1-S1).

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

Spinal Simplicity's Posterior Fusion Plate

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Spinal Simplicity LLC
6600 College Blvd
Suite 220
Overland Park, KS 66211
Phone: (913) 451-4414
Facsimile: (913) 888-0075

Contact Person: Adam Rogers

Date Prepared: November 18th, 2020

Name of Device:

Posterior Fusion Plate
HA Posterior Fusion Plate

Common / Classification Name:

21 CFR 888.3050: Spinal interlaminal fixation orthosis, Class II
Product codes: PEK, Spinous Process Plate

Predicate Devices:

Spinal Simplicity's HA Minuteman G3 MIS Fusion Plate (K151741) – Primary Predicate
Spinal Simplicity's Minuteman G3 MIS Fusion Plate (K140046) – Additional Predicate
Spinal Simplicity's HA Minuteman G3-R MIS Fusion Plate (K163428) – Additional Predicate

Intended Use / Indications for Use:

The Spinal Simplicity Posterior Fusion Plate is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation); and/or
- tumor.

The Posterior Fusion Plate is intended for use with bone graft material and is not intended for standalone use. The device may be implanted via a minimally invasive posterior approach (T1-S1) or a minimally invasive lateral approach (L1-S1).

Technological Characteristics:

The Posterior Fusion Plate consists of bilateral Plates and a Body/Post that connects the Plates, identical to the predicate construct. The Plate components include several spiked grips at the ends of each Plate for attachment to the spinous processes. The Posterior Fusion Plate device is available in multiple sizes to accommodate varying patient anatomy. The Posterior Fusion Plate is made from Ti6Al4V and Ti6Al4V ELI. The HA Posterior Fusion Plate has an additional hydroxyapatite coating on the distal regions of the device.

Performance Data:

Test data and/or engineering analyses have been provided to describe the performance of the Posterior Fusion Plate in the following test modalities:

- ASTM F1717 Static Axial Compression
- ASTM F1717 Static Torsion
- ASTM F1717 Dynamic Axial Compression

The data demonstrate that the subject Posterior Fusion Plate device presents substantially equivalent mechanical performance compared to the predicate device.

Bacterial endotoxin testing will be performed on all batches of sterile packed devices.

Cadaveric device insertion data was presented to demonstrate the suitability of the surgical insertion technique for the device's listed indications. The data demonstrate that the device may be inserted with minimal risk of spinous process fracture.

Data from a surgeon-involved cadaveric implantation study was presented to demonstrate suitable device function and performance.

Survey data from surgeons outside the United States who have implanted the device was also presented and show that none of the surgeons observed any instances of failure to deploy the device wings, spinous process fracture, or neurological injuries.

Clinical data were presented to demonstrate that the risk of device migration, dislodgement, and spinous process fracture were sufficiently low.

Substantial Equivalence:

The Posterior Fusion Plate has the same intended use, the same indications for use, and similar technological characteristics and principles of operation as its predicate device.

Differences between the subject and predicate device are minor and do not raise any new issues of safety or effectiveness. Performance data further demonstrate that the Posterior Fusion Plate is substantially equivalent to the predicate device.

Conclusions:

The information submitted by Spinal Simplicity in this premarket notification demonstrates that the Posterior Fusion Plate performs as intended and is substantially equivalent to the predicate device.