DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 20, 2015

Spinal Simplicity, LLC
% Ms. Janice M. Hogan
Hogans Lovells US, LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K151741
Trade/Device Name: HA Minuteman G3 MIS Fusion Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: June 26, 2015
Received: June 26, 2015

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K151741

Device Name

HA Minuteman G3 MIS Fusion Plate

Indications for Use *(Describe)*

The Spinal Simplicity HA Minuteman G3 MIS 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 radio-graphic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation); and/or
- tumor.

The HA Minuteman G3 MIS Fusion Plate is intended for use with bone graft material and is not intended for stand-alone 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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Spinal Simplicity's HA Minuteman G3 MIS Fusion Plate

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

Spinal Simplicity LLC
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Overland Park, KS 66210
Phone: (913) 451 4414
Facsimile: (913) 888 0075

Contact Person: Julie McKee, J.D.

Date Prepared: August 18, 2015

Name of Device

HA Minuteman G3 MIS Fusion Plate

Common / Classification Name

Spinous Process Plate, 21 CFR 888.3050, Class II
Product codes: PEK

Predicate Device

Spinal Simplicity's Spinous Process Fusion Plate (K140046)

Intended Use / Indications for Use

The Spinal Simplicity HA Minuteman G3 MIS 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 radio-graphic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation); and/or
- tumor.

The HA Minuteman G3 MIS Fusion Plate is intended for use with bone graft material and is not intended for stand-alone use. The device may be implanted via a minimally invasive posterior approach (T1-S1) or a minimally invasive lateral approach (L1-S1).

Device Description

The HA Minuteman G3 MIS Fusion Plate consists of bilateral Plates and a Body/Post that connects the Plates, identical to the predicate construct. The Plate components include several spikes at the ends of each Plate for attachment to the spinous processes. The HA

Minuteman G3 device is available in multiple sizes to accommodate varying patient anatomy. The HA Minuteman G3 is made from Ti6Al4V (per ASTM F1472) and Ti6Al4V ELI (per ASTM F136) and has a hydroxyapatite coating (per ASTM F1185) at the distal regions of the plate.

Performance Data

The HA powder was characterized to determine its particle size, Ca/P ratio, elemental analysis, solubility, dissolution products and rates, XRD pattern (per ASTM F2024), and FTIR spectra. The HA coating was characterized to determine its porosity, thickness (via SEM), Ca/P ratio, elemental analysis, static shear strength (per ASTM F1160), static tensile strength (per ASTM 1147), solubility, dissolution products and rates, XRD pattern (per ASTM F2024), and FTIR spectra.

In all instances, the subject device functioned as intended and the results observed were as expected. Further, engineering rationales and modified performance testing per ASTM F1717 demonstrated that the HA Minuteman G3 presents substantially equivalent mechanical strength compared to the predicate device.

Substantial Equivalence

The Spinal Simplicity HA Minuteman G3 MIS Fusion Plate is as safe and effective as the identified predicate device. The Spinal Simplicity HA Minuteman G3 has the same intended use and indications for use, and similar technological characteristics and principles of operation as its predicate device. The subject device differs from the predicate in the addition of a hydroxyapatite coating at the distal regions of the plate, which does not raise any new issues of safety or effectiveness. Performance data demonstrate that the HA Minuteman G3 is substantially equivalent to the predicate device.

Conclusions

Therefore, the information submitted by Spinal Simplicity in this premarket notification demonstrates that the HA Minuteman G3 MIS Fusion Plate performs as intended and is substantially equivalent to the predicate device.