DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Febraury 2, 2017

Spinal Simplicity
Mr. Douglas B. Snell
Director of Engineering, Quality, and Regulatory
10995 Quivira Road
Overland Park, Kansas 66210

Re: K163428
Trade/Device Name: HA Minuteman G3-R MIS Fusion Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: January 6, 2017
Received: January 9, 2017

Dear Mr. Snell:

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,

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)*
K163428

Device Name

HA Minuteman G3-R MIS Fusion Plate

Indications for Use *(Describe)*

The HA Minuteman G3-R 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 radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation); and/or
- tumor.

The HA Minuteman G3-R MIS Fusion Plate is intended for use with bone graft material and is not intended for stand-alone use. The HA Minuteman G3-R MIS Fusion Plate may be implanted via 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 HA Minuteman G3-R MIS Fusion Plate

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

Spinal Simplicity
10995 Quivira Road
Overland Park, KS 66210
Phone: (913) 451 4414
Facsimile: (913) 888 0075
Contact Person: Douglas B Snell
Date Prepared: January 6th, 2016

Name of Device

HA Minuteman G3-R MIS Fusion Plate

Common or Usual Name

Spinous Process Plate, 21 CFR 888.3050, Class II
Product Code PEK

Primary Predicate Device

Spinal Simplicity HA Minuteman G3 MIS Fusion Plate (K151741)

Indications for Use

The HA Minuteman G3-R 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 radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation); and/or
- tumor.

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

Technological Characteristics

The HA Minuteman G3-R MIS Fusion Plate consists of bilateral Plates and a Body/Post that connects the Plates. The Plate components include several spikes on the face of each Plate for attachment to the spinous processes. The HA Minuteman G3-R device is available in multiple sizes to accommodate varying patient anatomy. The HA Minuteman G3-R is made from Ti6Al4V and Ti6Al4V ELI and has a hydroxyapatite coating on a portion of the implant.

Purpose of 510(k)

The purpose of this 510(k) is to:

- Introduce a two-part Body/Post component that allows for reduction of the non-load bearing lateral profile of the implant remaining in the patient. The outer threaded portion of the Body/Post remains nearly identical to the Body/Post of the predicate device, with the exception of several geometric features that allow the two halves of the Body/Post to be reversibly locked together.
- Introduce a feature that joins the Spike Plate and Hex Nut together as a single unit. This allows the user to hold the implant vertically with the nose of the device pointing towards the ground without the Spike Plate sliding down the Body/Post. This makes loading bone graft material into the device easier, as the user does not need to hold the Spike Plate out of the way.
- Update Wing geometry for manufacturing and to improve Wing profile in the closed and open positions.
- Make minor instrumentation updates.

Performance Data

The following tests have been performed on the HA Minuteman G3-R MIS Fusion Plate to evaluate the mechanical performance of the device:

- Static Axial Compression Test
- Static Torsion Test
- Dynamic Axial Compression Test
- Static Axial Pull-Out Test
- Static Plate Dissociation Test
- Simulated Deployment Testing
- Custom Body Connection Feature Tests (Torque Test, Axial Locking Feature Test, Axial Disengagement Test)
- Cadaveric Insertion Testing

In all instances, the HA Minuteman G3-R MIS Fusion Plate functioned as intended and the results observed were as expected.

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

Substantial Equivalence

The HA Minuteman G3-R MIS Fusion Plate has the same indications and similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the HA Minuteman G3-R MIS Fusion Plate and its predicate device do not raise different issues of safety or effectiveness, as confirmed through risk analysis and design control activities. Thus, we believe the HA Minuteman G3-R MIS Fusion Plate is substantially equivalent.

Conclusions

The HA Minuteman G3-R MIS Fusion Plate is substantially equivalent to the predicate device.