December 15, 2021

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

Re: K212781
Trade/Device Name: Posterior Fusion Plate/HA Posterior Fusion Plate, Minuteman G3 MIS Fusion Plate, HA Minuteman G3 MIS Fusion Plate, 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: November 17, 2021
Received: November 18, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212781

Device Name
Posterior Fusion Plate / HA 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:

• Lumbar spinal stenosis;
• 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 lateral approach (L1-S1) or a minimally invasive posterior approach (T1-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.

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)*
K212781

Device Name
Spinal Simplicity Minuteman G3 MIS Fusion Plate

Indications for Use *(Describe)*
The Spinal Simplicity 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:

- Lumbar spinal stenosis;
- 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 Minuteman G3 MIS 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 lateral approach (L1-S1) or a minimally invasive posterior approach (T1-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)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K212781

Device Name
Spinal Simplicity 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:

• Lumbar spinal stenosis;
• 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 MIS 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 lateral approach (L1-S1) or a minimally invasive posterior approach (T1-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)

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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)*
K212781

Device Name
Spinal Simplicity HA Minuteman G3-R MIS Fusion Plate

Indications for Use *(Describe)*
The Spinal Simplicity 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:

• Lumbar spinal stenosis;
• 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 standalone use. The device 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 Minuteman MIS Fusion Plate Implant System

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: December 9, 2021

Name of Device:

Minuteman MIS Fusion Plate Implant Family
- Minuteman G3 MIS Fusion Plate
- HA Minuteman G3 MIS Fusion Plate
- HA Minuteman G3-R MIS Fusion Plate
- Posterior Fusion Plate / HA Posterior Fusion Plate

Common / Classification Name:

Spinous Process Plate, 21 CFR 888.3050 - Spinal Interlaminal Fixation Orthosis, Class II
Product codes: PEK

Predicate Devices:

Primary Predicate Device:
- Spinal Simplicity's Posterior Fusion Plate / HA Posterior Fusion Plate (K200066)

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

Device Description:

The Minuteman devices consist of bilateral Plates and a Body/Post that connects the Plates, identical to the predicate constructs. The Plate components include several spiked grips at the ends of each Plate for attachment to the spinous processes. The Minuteman devices are available in multiple sizes to accommodate varying patient anatomy. The Minuteman devices are made

from Ti6Al4V and Ti6Al4V ELI. The HA versions of the Minuteman devices have an additional hydroxyapatite coating on the distal regions of the device.

The purpose of this submission is to update the Indications for Use. No technological, engineering, performance, or material changes have been made to the devices since being granted 510(k) clearance.

Intended Use / Indications for Use:

- Spinal Simplicity Posterior Fusion Plate / HA Posterior Fusion Plate:

  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:

  - Lumbar spinal stenosis;
  - 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 lateral approach (L1-S1) or a minimally invasive posterior approach (T1-S1).

- Spinal Simplicity Minuteman G3 / HA Minuteman G3:

  The Spinal Simplicity Minuteman G3 / 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:

  - Lumbar spinal stenosis;
  - 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 Minuteman G3 / HA Minuteman G3 MIS 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 lateral approach (L1-S1) or a minimally invasive posterior approach (T1-S1).

- Spinal Simplicity HA Minuteman G3-R

  The Spinal Simplicity 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:

  - Lumbar spinal stenosis;
  - 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 standalone use. The device may be implanted via a minimally invasive lateral approach (L1-S1).

Technological Characteristics:

There are no changes to the technological characteristics from the previously cleared versions of each Minuteman device. The only differences are labeling updates.

Performance Data:

There are no changes to the functional characteristics from the previously cleared versions of each Minuteman device. The only differences are labeling updates. Therefore, no non-clinical performance data has been submitted.

Clinical Data:

Clinical data from a prospective, randomized clinical study of the Minuteman was presented. The Minuteman was compared to surgical decompression in the treatment of skeletally-mature patients diagnosed with lumbar spinal stenosis with or without accompanying spondylolisthesis. The data showed that the Minuteman provided satisfactory clinical outcomes.

Substantial Equivalence:

The Spinal Simplicity Minuteman family of implants subject to this 510(k) notice are the same as the predicate devices cleared under K140046, K151741, K163428, and K200066. The only difference is regarding updated Indications for Use. The provided clinical data and information from the previous 510(k) applications support the conclusion that the subject devices with updated Indications for Use are substantially equivalent to the previously cleared predicate devices.

Conclusions:

The information submitted by Spinal Simplicity in this premarket notification demonstrates that the Minuteman implants perform as intended and are substantially equivalent to the predicate devices.