November 29, 2023

Spinal Simplicity LLC
Mr. Adam Rogers
Vice President of Regulatory and Engineering
6363 College Blvd
Ste 320
Overland Park, Kansas 66211

Re: K233527
Trade/Device Name: Minuteman G5 MIS Fusion Plate; Minuteman G1 (Posterior Fusion Plate /HA Posterior Fusion Plate); HA Minuteman G3-R MIS Fusion Plate; Minuteman G3/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: November 1, 2023
Received: November 1, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233527

Device Name

Minuteman G5 MIS Fusion Plate;
Minuteman G1 (Posterior Fusion Plate /HA Posterior Fusion Plate);
HA Minuteman G3-R MIS Fusion Plate;
Minuteman G3/HA Minuteman G3 MIS Fusion Plate

Indications for Use *(Describe)*

The Minuteman G5 MIS Fusion Plate is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving instrumented posterior arthrodesis (i.e., 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); and/or
• spondylolisthesis.

The Minuteman G5 MIS Fusion Plate is intended for use with bone graft material. The device may be implanted via a lateral transverse approach (L1-S1) or a posterior approach (T1-S1).

The Minuteman G1 (Posterior Fusion Plate/HA Posterior Fusion Plate) is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving instrumented posterior arthrodesis (i.e., 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); and/or
• spondylolisthesis.

The Minuteman G1 (Posterior Fusion Plate/HA Posterior Fusion Plate) is intended for use with bone graft material. The device may be implanted via a lateral transverse approach (L1-S1) or a posterior approach (T1-S1).

The HA Minuteman G3-R MIS Fusion Plate is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (T1-S1). It is intended for plate fixation/ attachment to spinous processes for the purpose of achieving instrumented posterior arthrodesis (i.e., 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); and/or
• spondylolisthesis.

The HA Minuteman G3-R MIS Fusion Plate is intended for use with bone graft material. The device may be implanted via a lateral transverse approach (L1-S1).

The Minuteman G3/HA Minuteman G3 MIS Fusion Plate is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving instrumented posterior arthrodesis (i.e., 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); and/or
• spondylolisthesis.

The Minuteman G3/HA Minuteman G3 MIS Fusion Plate is intended for use with bone graft material. The device may be implanted via a lateral transverse approach (L1-S1) or a 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.

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

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510(k) Summary

Prepared on: 2023-11-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Spinal Simplicity LLC
Applicant Address	6363 College Blvd Ste 320 Overland Park KS 66211 United States
Applicant Contact Telephone	913-451-4414
Applicant Contact	Mr. Adam Rogers
Applicant Contact Email	arogers@spinalsimplicity.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Minuteman G5 MIS Fusion Plate; Minuteman G1 (Posterior Fusion Plate /HA Posterior Fusion Plate); HA Minuteman G3-R MIS Fusion Plate; Minuteman G3/HA Minuteman G3 MIS Fusion Plate
Common Name	Spinous Process Plate
Classification Name	Spinous Process Plate
Regulation Number	888.3050
Product Code	PEK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221023	Minuteman MIS Fusion Plate Implants	PEK

Device Description Summary

21 CFR 807.92(a)(4)

The Minuteman MIS Fusion Plate Implants consist of bilateral Plates and a Body/Post that connects the Plates. The Plate components include several gripping features for attachment of the device to the spinous processes. The Minuteman MIS Fusion Plate Implants are available in multiple sizes to accommodate varying patient anatomy. The Minuteman MIS Fusion Plate Implants are made from Ti6Al4V and Ti6Al4V ELI. The HA versions of the Minuteman MIS Fusion Plate Implants 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, material or packaging changes have been made to the devices.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Minuteman G5 MIS Fusion Plate is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving instrumented posterior arthrodesis (i.e., 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); and/or

• spondylolisthesis.

The Minuteman G5 MIS Fusion Plate is intended for use with bone graft material. The device may be implanted via a lateral transverse approach (L1-S1) or a posterior approach (T1-S1).

The Minuteman G1 (Posterior Fusion Plate/HA Posterior Fusion Plate) is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving instrumented posterior arthrodesis (i.e., 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); and/or
• spondylolisthesis.

The Minuteman G1 (Posterior Fusion Plate/HA Posterior Fusion Plate) is intended for use with bone graft material. The device may be implanted via a lateral transverse approach (L1-S1) or a posterior approach (T1-S1).

The HA Minuteman G3-R MIS Fusion Plate is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving instrumented posterior arthrodesis (i.e., 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); and/or
• spondylolisthesis.

The HA Minuteman G3-R MIS Fusion Plate is intended for use with bone graft material. The device may be implanted via a lateral transverse approach (L1-S1).

The Minuteman G3/HA Minuteman G3 MIS Fusion Plate is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving instrumented posterior arthrodesis (i.e., 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); and/or
• spondylolisthesis.

The Minuteman G3/HA Minuteman G3 MIS Fusion Plate is intended for use with bone graft material. The device may be implanted via a lateral transverse approach (L1-S1) or a posterior approach (T1-S1).

Indications for Use Comparison 21 CFR 807.92(a)(5)

The purpose of this submission is to modify the Indications for Use statement. The modifications to the Indications for Use statement do not constitute a new intended use of the device. The modifications to the Indications for Use statement do not affect the safety and effectiveness of the Minuteman MIS Fusion Plate Implants. The Minuteman MIS Fusion Plate Implants with the updated Indications for Use are substantially equivalent to the previously cleared predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The Minuteman MIS Fusion Plate Implants have the same technological characteristics (same design, material composition, packaging, principles of operations) as the cleared predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical and/or Clinical Tests were not performed as part of this submission. The Minuteman MIS Fusion Plate Implants with the updated Indications for Use are substantially equivalent to the previously cleared predicate devices.