



April 19, 2024

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

Re: K232259

Trade/Device Name: Patriot-SI Posterior Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: March 11, 2024
Received: March 11, 2024

Dear Adam 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

Indications for Use

510(k) Number (if known)

K232259

Device Name

Patriot-SI Posterior Implant System

Indications for Use (Describe)

The Patriot-SI Posterior Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. When the Patriot-SI Posterior Implant System (i.e., an “in-line” or “intra-articular” device) is implanted, it must be used with a Spinal Simplicity Liberty-SI Lateral System device (i.e., a “transfixing” device) implanted across the same sacroiliac joint to create a hybrid SI joint fusion construct.

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) #: K232259

510(k) Summary

Prepared on: 2024-03-13

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Patriot-SI Posterior Implant System
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Common Name	Smooth or threaded metallic bone fixation fastener
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Classification Name	Sacroiliac Joint Fixation
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Regulation Number	888.3040
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Product Code	OUR
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Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190580	NADIA® SI Fusion System	OUR

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Patriot-SI Posterior Implant System is a minimally invasive sacroiliac joint fusion implant that is intended for implantation on a trajectory in line with the joint space (i.e., the device is an in-line or intra-articular implant). The Patriot-SI Posterior Implant System device is required to be implanted with the Spinal Simplicity Liberty-SI Lateral System device implanted across the same sacroiliac joint to create a hybrid SI joint fusion construct for the purpose of stabilizing and fusing the sacroiliac joint. It is available in one size and may be implanted using the designated surgical instruments through a posterior approach into the SI joint space, fixating on both the sacrum and ilium via external threads. Bone graft materials may be used with the Patriot-SI Posterior Implant System. The Patriot-SI Posterior Implant System device is made from additively manufactured titanium alloy, Ti-6Al-4V-ELI per ASTM F3001 and is offered with or without a hydroxyapatite (HA) coating per ASTM F1185. The Patriot-SI Posterior Implant System device is provided sterile and individually packed.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Patriot-SI Posterior Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. When the Patriot-SI Posterior Implant System (i.e., an "in-line" or "intra-articular" device) is implanted, it must be used with a Spinal Simplicity Liberty-SI Lateral System device (i.e., a "transfixing" device) implanted across the same sacroiliac joint to create a hybrid SI joint fusion construct.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The Patriot-SI Posterior Implant System has the same indications for use as the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The Patriot-SI Posterior Implant System is as safe and effective as the identified predicate device. The Patriot-SI Posterior Implant System has the same technological characteristics and surgical approach as its predicate device. Performance testing demonstrates that the Patriot-SI Posterior Implant System is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non clinical mechanical tests were performed to support substantial equivalence of the Patriot-SI Posterior Implant System. Cadaver testing was also performed to support the performance of the Patriot-SI Posterior Implant System. The following tests were performed:

- ASTM F3574 Static Shear Testing
- ASTM F3574 Static and Dynamic Torsion Testing
- ASTM F3574 Static Pushout Testing
- ASTM F3574 Driving Torque Testing
- ASTM F2077 Static and Dynamic Compression-Shear Testing

Clinical performance testing was not performed for this submission.

Spinal Simplicity concludes that the performance testing provided in this 510(k) application demonstrates that the Patriot-SI Posterior Implant System is capable of performing as intended and is as safe and effective as the legally marketed predicate device.