December 5, 2023

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

Re: K231923
Trade/Device Name: Liberty SI Lateral 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: November 6, 2023
Received: November 6, 2023

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

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)*
K231923

Device Name
Liberty SI Lateral Implant System

Indications for Use *(Describe)*
The Liberty SI Lateral Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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: 2023-12-05

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	Liberty SI Lateral Implant System
Common Name	Sacroiliac Joint Fixation
Classification Name	Smooth or threaded metallic bone fixation fastener
Regulation Number	888.3040
Product Code	OUR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183119	SI-LOK® Sacroiliac Joint Fixation System	OUR

Device Description Summary

21 CFR 807.92(a)(4)

The Liberty SI Lateral Implant System is a minimally invasive sacroiliac joint fusion implant that is intended for implantation across the joint space (i.e., the implant transfixes the SI joint). The Liberty SI Lateral Implant System is composed of Ti-6Al-4V ELI titanium alloy per ASTM F136 and is partially coated with hydroxyapatite (HA) per ASTM F1185. To accommodate varying patient anatomy, the Liberty SI Lateral Implants are available in multiple diameters and length offerings. The Liberty SI Lateral Implants consist of a cannulated central threaded body that has deployable Wings and a Compressive Body. Using the designated instrument system, one or two implants may be inserted across the SI Joint to apply a compressive force across the joint and to provide stabilization and fusion. The Liberty SI Lateral Implants are single use devices that are provided sterile.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Liberty SI Lateral Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Liberty SI Lateral Implant System has the same indications for use as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The Liberty SI Lateral Implant System is substantially equivalent to the identified predicate device. The Liberty SI Lateral Implant System has a similar surgical approach, materials, range of sizes, design and principles of operation compared to its predicate device. Any

differences in technological characteristics do not raise different questions of safety or effectiveness. Performance testing demonstrates the device has mechanical performance substantially equivalent to that of the predicate.

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

Non-clinical mechanical tests per ASTM F3574 were performed to support substantial equivalence of the Liberty SI Lateral Implant System. Custom and cadaver tests were also performed to support the performance of the device.

The following ASTM F3574 tests were performed:
ASTM F3574 Static Cantilever Bend Testing
ASTM F3574 Static Torsion Testing
ASTM F3574 Pullout Strength Testing
ASTM F3574 Driving Torque Testing
ASTM F3574 Dynamic Cantilever Bend 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 Liberty SI Lateral Implant System is capable of performing as intended and is substantially equivalent to the legally marketed predicate device.