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

May 24, 2024

Re: K240592
Trade/Device Name: Wolff's Law Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 1, 2024
Received: March 1, 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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.05.24 13:52:10 -04'00'

for

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)*

K240592

Device Name

Wolff's Law Anterior Cervical Plate System

Indications for Use *(Describe)*

The Wolff's Law Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

• Degenerative Disc Disease (DDD) – as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
• Spondylolisthesis;
• Spinal Stenosis;
• Trauma (including fractures);
• Tumor;
• Deformity (i.e., scoliosis, kyphosis, and/or lordosis);
• Pseudoarthrosis; and
• Failed previous fusions

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.

510(k) Summary

Prepared on: 2024-05-21

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	Wolff's Law Anterior Cervical Plate System
Common Name	Spinal intervertebral body fixation orthosis
Classification Name	Appliance, Fixation, Spinal Intervertebral Body
Regulation Number	888.3060
Product Code(s)	KWQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K083020	DynaTran™ Anterior Cervical Plating (ACP) System	KWQ
K143626	SC-AcuFix® Ant-Cer Dynamic Cervical Plating System	KWQ
K051665	Synthes Vectra-T System	KWQ

Device Description Summary

21 CFR 807.92(a)(4)

The Spinal Simplicity Wolff's Law Anterior Cervical Plate System is a dynamic cervical plate designed for attachment to the anterior cervical spine (C2-C7). The Wolff's Law Plate System consists of one-level to four-level plates in multiple lengths with both fixed- and variable-angle screws. The plates are translatable and use a nitinol Compression Element to provide continuous compression at each level. The Wolff's Law Cervical Plate consists of components made from titanium alloy Ti6Al4V ELI per ASTM F136 and superelastic nitinol per ASTM F2063. The fixed and variable screws are made from Titanium alloy Ti6Al4V ELI per ASTM F136. The Wolff's Law Anterior Cervical Plate System is provided to the end-user sterile and is single use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Wolff's Law Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

• Degenerative Disc Disease (DDD) – as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
• Spondylolisthesis;
• Spinal Stenosis;
• Trauma (including fractures);
• Tumor;

• Deformity (i.e., scoliosis, kyphosis, and/or lordosis);
• Pseudoarthrosis; and
• Failed previous fusions

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the primary and secondary predicate devices fully encompasses the Wolff's Law Anterior Cervical Plate System indication for use statement. The types of conditions for which the Wolff's Law Anterior Cervical Plate System is used are identical to the predicate devices. The slight differences in the indications for use statements do not constitute a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The Wolff's Law Anterior Cervical Plate System has similar technological characteristics, surgical approach, materials, range of sizes, design and principles of operation as the predicate devices. 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 were performed to support the substantial equivalence of the Wolff's Law Anterior Cervical Plate System. Custom test were also performed to support the performance and substantial equivalence of the device. FDA Guidance Document Spinal Plating Systems - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff was used to support the performance testing and the following ASTM test were performed:

ASTM F1717 Static Compression Bending
ASTM F1717 Static Torsion
ASTM F1717 Static Tension Bending
ASTM F1717 Dynamic Compression Bending
ASTM F543 Axial Screw Pullout/Pushout
ASTM F2129 & ASTM F3044 Corrosion Testing
ASTM F1877 Particulate Analysis
ASTM F2004 Transformational Temperature

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 Wolff's Law Anterior Cervical Plate System is capable of performing as intended and is substantially equivalent to the legally marketed predicate device.