May 23, 2025

SpineUp, Inc.
Kyle Atwood
VP of Quality and Regulatory Assurance
1954 North 30th Road
Suite B
Hollywood, Florida 33021

Re: K250446
Trade/Device Name: Frida™ 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: April 30, 2025
Received: April 30, 2025

Dear Kyle Atwood:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

STEPHANIE SMITH -S

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)*

K250446

Device Name

Frida™ Anterior Cervical Plate System

Indications for Use *(Describe)*

The Frida™ Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine in skeletally mature patients, serving as an adjunct to fusion of the cervical spine (C2 - T1). The system is intended for the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: 1) degenerative disc disease (as defined as neck pain of discogenic origin and confirmed by patient history and radiographic studies), 2) spondylolisthesis, 3) spinal stenosis, 4) trauma, 5) failed previous fusions, 6) tumors, 7) curvature deformities (kyphosis, lordosis, or scoliosis), and/or 8) pseudoarthrosis.

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) #: K250446

510(k) Summary

Prepared on: 2025-04-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SpineUp, Inc.
Applicant Address	1954 North 30th Road Suite B Hollywood FL 33021 United States
Applicant Contact Telephone	786-910-0234
Applicant Contact	Mr. Philippe Laurito
Applicant Contact Email	philippe.l@upgroup.tech
Correspondent Name	SpineUp, Inc.
Correspondent Address	1954 North 30th Road Suite B Hollywood FL 33021 United States
Correspondent Contact Telephone	435-512-6808
Correspondent Contact	Mr. Kyle Atwood
Correspondent Contact Email	kyle.a@upgroup.tech

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Frida™ 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
K160702	ZION Anterior Cervical Fixation System	KWQ
K222572	Rex Anterior Cervical Plate System	KWQ
K080646	C-TEK MAXAN ANTERIOR CERVICAL PLATE SYSTEM	KWQ

Device Description Summary

21 CFR 807.92(a)(4)

The Frida™ Anterior Cervical Plate System is an anterior cervical plating system that consists of single-use plates and screws, along with manual instruments for implant insertion. The plates are manufactured from titanium (Ti-6Al-4V ELI) per ASTM F136 and come in a variety of lengths to accommodate individual pathology and anatomical conditions of the patient. Plates incorporate a graft window for intraoperative visualization. Screws are manufactured from titanium (Ti-6Al-4V ELI) per ASTM F136 and are available in self-tapping and self-drilling options. Screws are available in a fixed or variable configuration, with a range of sizes to accommodate individual pathology. Plates and screws are available in single-use sterile packaging.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Frida™ Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine in skeletally mature patients, serving as an adjunct to fusion of the cervical spine (C2 - T1). The system is intended for the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: 1) degenerative disc disease (as defined as neck pain of discogenic origin and confirmed by patient history and radiographic studies), 2) spondylolisthesis, 3) spinal stenosis, 4) trauma, 5) failed previous fusions, 6) tumors, 7) curvature deformities (kyphosis, lordosis, or scoliosis), and/or 8) pseudoarthrosis.

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

The Frida™ Anterior Cervical Plate System has identical indications for use as the primary predicate device and has similar indications for use as the additional predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The Frida™ 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 devices.

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

Mechanical testing was performed to demonstrate substantial equivalence using static compression, dynamic compression, and static torsion testing per ASTM F1717.

The results of mechanical testing showed that the worst-case constructs were substantially equivalent to legally marketed devices.