January 10, 2022

SpineUp Inc.
Ryan Weitzel
VP of Quality Assurance & Regulatory Affairs
100 North Biscayne Blvd. Suite 3070
Miami, Florida 33132

Re: K212358
Trade/Device Name: Romero Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: December 10, 2021
Received: December 13, 2021

Dear Ryan Weitzel:

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 (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 located 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.

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

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

Brent Showalter, Ph.D.
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)*
K212358

Device Name
Romero Cervical Cage

Indications for Use *(Describe)*
The Romero Cervical Cage consists of an interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one or two contiguous levels from the C2 to the T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Romero Cervical Cage includes cages with and without screw holes. For cages with internal screw holes, the provided screws must be used for internal fixation. The Romero Cervical Cage requires additional supplemental fixation cleared for the cervical spine. The Romero Cervical Cage is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

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

Submitter's Name:	SpineUp, Inc
Submitter's Address:	100 North Biscayne Blvd Suite 3070 Miami, FL 33132
Submitter's Telephone:	(786) 910-0234
Company Contact Person:	Philippe Laurito
Contact Person:	Ryan Weitzel VP of Quality Assurance and Regulatory Affairs ryan.w@upgroup.tech
Date Summary was Prepared:	1/7/2022
Trade or Proprietary Name:	Romero Cervical Cage
Common or Usual Name:	Intervertebral body fusion device
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVE, ODP
Classification Panel:	Division of Orthopedic Devices
Panel Code:	87

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Romero Cervical Cage is an anterior cervical interbody device consisting of a PEEK HA or PEEK OPTIMA interbody cage with tantalum radiographic markers and two Titanium (Ti-6Al-4V ELI) fixation screws for cages with screw holes. The PEEK material used conforms to ASTM F2026, the Titanium screws conforms to ASTM F136 and the Tantalum radiographic markers conforms to ASTM F560. The interbody cage is provided in 6º lordosis, anatomic (domed), and lordotic (tapered) profiles in footprints ranging from (WxD) 14x12 to 20x16 (by increments of 2 mm in either direction) and sizes ranging from 5.5 mm (H04) to 14.5 mm (H13) (excluding H04 and H05 in the (WxD) 14x12 to 14x16 footprint for the self-anchored cages). The two radiographic markers are present on the posterior wall to confirm position and orientation relative to the AP plane. The bone screws are provided as self-drilling and self-tapping options in 3.5 mm and 4.0 mm diameters and 8-20 mm lengths and feature an anti-backout / tri-lobe screw head design. Both cages and screws are available in separate, single-use sterile packaging.

INDICATIONS FOR USE ROMERO CERVICAL CAGE

The Romero Cervical Cage consists of an interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one or two contiguous levels from the C2 to the T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Romero Cervical Cage includes cages with and without screw holes. For cages with internal screw holes, the provided screws must be used for internal fixation. The Romero Cervical Cage requires additional supplemental fixation cleared for the cervical spine. The Romero Cervical Cage is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

PREDICATES

Romero Cervical Cage is substantially equivalent to the Medtronic DIVERGENCE™ Anterior Cervical Fusion System (K141599). The Romero Cervical Cage is provided sterile. The subject and predicate devices have identical technological characteristics. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use (equivalent to Primary and Additional predicates)
- Materials of manufacture (combination of Primary predicate and FDA MAF references)
- Structural support mechanism (identical to Additional Predicate)

Table 6-1: Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Type
K141599 (Primary)	DIVERGENCE™ Anterior Cervical Fusion System	Medtronic Sofamor Danek USA, Inc.	OVE - Intervertebral body fusion device
K173102 (Additional)	Reliance Cervical IBF System	Reliance Medical Systems, LLC	ODP, OVE - Intervertebral body fusion device
K202812 (Additional)	IdentiTi™ Cervical Standalone Interbody System	Alphatec Spine, Inc.	OVE - Intervertebral body fusion device
K142079 (Additional)	STALIF C®	Centinel Spine, Inc.	OVE - Intervertebral body fusion device

PERFORMANCE TESTING

SpineUp's Romero Cervical Cage was evaluated to demonstrate equivalence to the primary predicate device as well as the additional predicates for features that were being combined in the new device. Mechanical testing was performed to demonstrate substantial equivalence using static compression, static compression shear, static torsion, dynamic compression, dynamic compression shear, and dynamic torsion testing per ASTM F2077-18. Subsidence testing per ASTM F2267-04, expulsion and axial push out testing.

The result showed that the worst-case constructs were substantially equivalent to legally marketed devices. No clinical or animal studies were performed.

CONCLUSION

SpineUp concludes that the Romero Cervical Cage is substantially equivalent to the already marketed predicate in regard to indications for use, materials, function, sizes and mechanical test results.