May 30, 2024

Spectrum Spine, Inc.
% Christine Scifert
Partner
MRC Global
9085 East Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K240838
Trade/Device Name: Spectrum Spine Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 22, 2024
Received: March 27, 2024

Dear Christine Scifert:

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,

Brent Showalter -S

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)*
K240838

Device Name
Spectrum Spine Cervical Cage System

Indications for Use *(Describe)*
The Spectrum Spine Cervical Cage System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. These patients should have had at least six weeks of nonoperative treatment. The Spectrum Spine Cervical Cage System is indicated to be used with supplemental fixation cleared by the FDA for use in the cervical spine and autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

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

Spectrum Spine Cervical Cage System

May 20, 2024

Company: Spectrum Spine, Inc.
20 Harmony Ct.
Jasper, GA 30143

Primary/Secondary Contact: Christine Scifert – Partner
MRC Global
9085 E. Mineral Cir., Suite 110
Centennial, CO 80112
Phone: (901) 831-8053
Email: christine.scifert@AskMRCGlobal.com

Jen McBride – Regulatory Consultant
(901) 481-5902
Email: jen.mcbride@askmcrglobal.com

Company Contact: Jim Sevey
[title]
Spectrum Spine, Inc.
Phone: (888) 377-7328
jsevey@spectrumspine.com

Trade Name: Spectrum Spine Cervical Cage System

Common Name: Intervertebral Fusion Device With Bone Graft, Cervical

Classification: Class II

Regulation: 21 CFR 888.3080 (Intervertebral Fusion Device)

Panel: Orthopedic

Product Code: ODP

Primary Predicate: Medtronic Sofamor Danek USA Inc. Endoskeleton TC Interbody System – K211258

Device Description:

The Spectrum Spine Cervical Cage System is composed of cervical interbody fusion devices. The Spectrum Spine Cervical Cage System is offered in five footprints with varying heights and lordotic angles designed to accommodate patient anatomy. Additionally, all interbody cages are offered with a smooth finish and

a rough finish. The interbody devices also contain a large graft window through the body of the device to allow for placement of bone graft and facilitate fusion. All implant components are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

The Spectrum Spine Cervical Cage System also includes instruments to facilitate implantation of the subject implant devices. Instruments are manufactured from medical grade stainless steel.

Indications for Use:

The Spectrum Spine Cervical Cage System devices including those with macro-, micro- and nano-roughened surface textured features are indicated for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. These patients should have had at least six weeks of nonoperative treatment. The Spectrum Spine Cervical Cage System is indicated to be used with supplemental fixation cleared by the FDA for use in the cervical spine and autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

Substantial Equivalence:

The subject Spectrum Spine Cervical Cage System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Medtronic Sofamor Danek USA Inc. Endoskeleton TC Interbody System– K211258; K100889

Additional Predicate:

- Eminent Spine Cervical Stand Alone System – K212853

Reference Predicate:

- Anjon Bremer Halo System - K193256

There are insignificant differences between the subject Spectrum Spine Cervical Cage System and the predicates. The Indications for Use, Materials, and Geometry for predicate devices are all inclusive of the subject device. Testing shows that the subject Spectrum Spine Cervical Cage performs equivalent to or better than previously cleared devices. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Mechanical testing, including static and dynamic axial compression, static and dynamic compression shear, and static and dynamic torsion per ASTM F2077-22, as well as subsidence per ASTM F2267-22 and expulsion have been performed on the subject Spectrum Spine Cervical Cage devices and the results have shown them to be substantially equivalent to the predicate interbody devices.

Conclusion:

The subject device is determined to be substantially equivalent to the predicate devices.