April 4, 2025

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

Re: K243074
Trade/Device Name: Spectrum Spine Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 27, 2024
Received: February 4, 2025

Dear Ms. 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.

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,

Katherine D. Kavlock -S

for
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243074

Device Name

Spectrum Spine Lumbar Cage System

Indications for Use *(Describe)*

The Spectrum Spine Lumbar Cage System devices with roughened surface textured features, are indicated for use in skeletally mature patients with lumbar degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion, confirmed by imaging studies (radiographs, CT, MRI). DDD is defined as discogenic pain with degeneration of the disc. DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had at least six months of nonoperative treatment. The Spectrum Spine Lumbar Cage System is indicated to be used with supplemental fixation cleared by the FDA for use in the lumbar 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.

K243074 - 510(k) Summary

Spectrum Spine Lumbar Cage System

March 28, 2025

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
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Company Contact: Scott Baltsen
COO
Spectrum Spine, Inc.
Phone: (888) 377-7328
sbaltsen@spectrumspine.com

Trade Name: Spectrum Spine Lumbar Cage System

Common Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Classification: Class II

Regulation: 21 CFR 888.3080 (Intervertebral Fusion Device)

Panel: Orthopedic

Product Code: MAX

Primary Predicate: Medtronic Sofamor Danek USA Inc. Endoskeleton TA Interbody System, Endoskeleton TAS & TAS Hyp Interbody System, Endoskeleton TL Interbody System, Endoskeleton TL Hyp. Interbody System, Endoskeleton TO Interbody System, Endoskeleton TT Interbody System – K211258

Device Description:

The Spectrum Spine Lumbar Cage System is composed of lumbar interbody fusion devices. The Spectrum Spine Lumbar Cage System is offered in multiple 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 Lumbar 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 Lumbar Cage System devices with roughened surface textured features, are indicated for use in skeletally mature patients with lumbar degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion, confirmed by imaging studies (radiographs, CT, MRI). DDD is defined as discogenic pain with degeneration of the disc. DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had at least six months of nonoperative treatment. The Spectrum Spine Lumbar Cage System is indicated to be used with supplemental fixation cleared by the FDA for use in the lumbar 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 Lumbar Cage System is substantially equivalent to the following predicate devices:

Primary Predicate:

Medtronic Sofamor Danek USA Endoskeleton TA Interbody System, Endoskeleton TAS & TAS Hyp Interbody System, Endoskeleton TL Interbody System, Endoskeleton TL Hyp. Interbody System, Endoskeleton TO Interbody System, Endoskeleton TT Interbody System – K211258

Additional Predicates:

Eminent Spine 3D Lumbar Interbody Fusion Systems – K230219
Spectrum Cervical Cage System – K240838
Anjon Bremer Molded Halo Crown – K193256
GSMedical Co, Ltd, AnyPlus T-PLIF PEEK Cages – K131612
Spectrum Spine Expandable Titanium PLIF/TLIF System – K201024; K173518

There are insignificant differences between the subject Spectrum Spine Lumbar Cage System and the predicates. The Indications for Use and Materials for predicate devices are all inclusive of the subject device. Geometry and design of the subject device is similar to that of the predicates. Testing shows that

the subject Spectrum Spine Lumbar 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 and static and dynamic compression shear per ASTM F2077-22, as well as subsidence per ASTM F2267-22 and expulsion have been performed on the subject Spectrum Spine Lumbar 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.