



October 24, 2025

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

Re: K253377

Trade/Device Name: Spectrum Spine Expandable Titanium PLIF/TLIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 30, 2025
Received: September 30, 2025

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.

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

Indications for Use

510(k) Number (if known)
K253377

Device Name

Spectrum Spine Expandable Titanium PLIF/TLIF System

Indications for Use (Describe)

The Spectrum Spine Expandable Titanium PLIF/TLIF System includes interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

Spectrum Spine Expandable Titanium PLIF/TLIF System implants are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation.

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.

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510(k) Summary
Spectrum Spine Expandable Titanium PLIF/TLIF System
October 22, 2025

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

Primary/Secondary Contact: Christine Scifert – Partner
MRC Global
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Company Contact: Scott Baltsen
COO
Spectrum Spine, Inc.
Phone: (888) 377-7328
sbaltsen@spectrumspine.com

Trade Name: Spectrum Spine Expandable Titanium PLIF/TLIF 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: Spectrum Spine Expandable Titanium PLIF/TLIF System

Device Description:

The Spectrum Spine Expandable Titanium PLIF/TLIF System consists of lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following

discectomy. The Expandable Titanium PLIF/TLIF System implants are provided in various shapes to accommodate posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF) surgical approaches. These implants can expand to a set height and lordosis as appropriate. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. The Expandable Titanium PLIF/TLIF System is to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

The Expandable Titanium PLIF/TLIF System is manufactured from titanium alloy per ASTM F136.

The system provides several footprints in multiple height and angle configurations. The cage's ability to be inserted at a nominal height and then expand to a set height and angle to fill the joint space once properly positioned minimizes damage to the bony end-plate caused by impaction.

The purpose of this special 510(k) is to gain clearance for modifications made to the Expandable Titanium PLIF/TLIF System.

Indications for Use:

The Spectrum Spine Expandable Titanium PLIF/TLIF System includes interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

Spectrum Spine Expandable Titanium PLIF/TLIF System implants are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation.

Substantial Equivalence:

The subject Spectrum Spine Expandable Titanium PLIF/TLIF System is substantially equivalent to the following predicate devices:

Primary Predicate:

Spectrum Spine Expandable Titanium PLIF/TLIF System – K201024

Additional Predicates:

Spectrum Cervical Cage System – K240838

Spectrum Lumbar Cage System – K243074

Anjon Bremer Molded Halo Crown – K193256

There are insignificant differences between the subject Spectrum Spine Expandable Titanium PLIF/TLIF System and the predicates. The Indications for Use, Materials, and overall Geometry for predicate device are identical to that of the subject device. Testing shows that the subject Spectrum Spine

Expandable Titanium PLIF/TLIF System performs equivalent to the previously cleared device. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Mechanical testing, including dynamic axial compression and dynamic compression shear per ASTM F2077-22, as well as expulsion have been performed on the subject Spectrum Spine Expandable Titanium PLIF/TLIF devices and the results have shown them to be substantially equivalent to the predicate device.

Conclusion:

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