March 30, 2026

Spectrum Spine
% Ethan Naylor
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street, NW
Washington, District of Columbia 20001

Re: K252240
Trade/Device Name: Spectrum Spine Cervical Cage System; Spectrum Spine Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: July 17, 2025
Received: March 6, 2026

Dear Mr.Naylor:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252240

Please provide the device trade name(s).

Spectrum Spine Cervical Cage System;
Spectrum Spine Lumbar Cage System

Please provide your Indications for Use below.

Spectrum Spine Cervical Cage System
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 cortico-cancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

Spectrum Spine Lumbar Cage System
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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Device Trade Name:	Spectrum Spine Cervical Cage System Spectrum Spine Lumbar Cage System
Manufacturer:	Spectrum Spine 20 Harmony Ct Jasper, GA 30143
Contact:	Dr. James C. Robinson Chief Executive Officer (404) 550-1334
Prepared by:	Ethan Naylor MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 571.396.1248 Email: ethan.naylor@mcra.com
Date Prepared:	March 26, 2026
Classifications:	21 CFR 88.3080, Intervertebral Body Fusion Device
Class:	II
Product Codes:	ODP MAX
Primary Predicate:	Spectrum Spine Cervical Cage System, Spectrum Spine, K240838
Additional Predicates:	Spectrum Spine Lumbar Cage System, Spectrum Spine, K243074 neoWave C Cervical, Xenix Medical, K222988

Purpose of the Submission:
The purpose of the subject 510(k) was to add nanotechnology claim in alignment with the FDA's Guidance on Nanotechnology.

Indications For Use:
Spectrum Spine Cervical Cage System
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 cortico-cancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

Spectrum Spine Lumbar Cage System
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.

Device Description:
Spectrum Spine Cervical Cage System
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 device incorporates Spectrum Spine's proprietary BioBraille nano-feature surface design to improve fixation to adjacent bone. The Spectrum Spine implant surfaces undergo a surface alteration to create features at the nanometer level (10^{-9}). These features have demonstrated the ability to elicit an endogenous cellular and biochemical response. These features meet the requirements of a nanotechnology as outlined by FDA nanotechnology guidance document.

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.

Spectrum Spine Lumbar Cage System
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 device incorporates Spectrum Spine's proprietary BioBraille nano-feature surface design to improve fixation to adjacent bone. The Spectrum Spine implant surfaces undergo a surface alteration to create features at the nanometer level (10^{-9}). These features have demonstrated the ability to elicit an endogenous cellular and biochemical response. These features meet the requirements of a nanotechnology as outlined by FDA nanotechnology guidance document.

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.

Predicate Device:
Spectrum submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Spectrum Spine Cervical Cage System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: Spectrum Spine Cervical Cage System, Spectrum Spine, K240838

Additional Predicates: Spectrum Spine Lumbar Cage System, Spectrum Spine, K243074
neoWave C Cervical, Xenix Medical, K222988

Additionally, Spectrum Spine Lumbar Cage System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: Spectrum Spine Lumbar Cage System, Spectrum Spine, K240838

Additional Predicates: Spectrum Spine Lumbar Cage System, Spectrum Spine, K243074
neoWave C Cervical, Xenix Medical, K222988

Performance Testing Summary:

In accordance with the recommendations in FDA's Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, imaging was used to demonstrate the presence of nanoscale surface features and an in vitro study was conducted to demonstrate the biological effect of the nanoscale surface features, represented by increased expression of Type I Collagen and Bone Sialoprotein in murine bone marrow stromal cells in vitro. In vitro performance may not be representative of clinical performance.

Substantial Equivalence:
The subject devices and predicate devices have the same intended use and technological characteristics:

- Intended use: Interbody fusion in skeletally mature patients.
- Principle of Operation: Restores intervertebral height, enables fusion, nano-roughened surface approves fixation to adjacent bone
- Material: Titanium Alloy
- Sterility: Sterile, gamma irradiated

Conclusion:
The subject devices and the predicate devices have the same intended use, have similar technological characteristics, and are made of identical materials. The subject and predicate devices are packaged in identical materials and are sterilized using identical methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. The Spectrum Spine Cervical and Lumbar Cage Systems are as safe, as effective, and perform as well as, or better, than the predicate devices.