May 10, 2022

SeaSpine Orthopedics Corporation
Kavita Chandrashekar
Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K220711
Trade/Device Name: SeaSpine Meridian System, SeaSpine Meridian Anterior Plate System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, KWQ
Dated: March 10, 2022
Received: March 11, 2022

Dear Kavita Chandrashekar:

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)*
K220711

Device Name
SeaSpine Meridian System

Indications for Use *(Describe)*

Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The SeaSpine Meridian System with NanoMetalene® surface technology interbody, when used with or without a Spin Plate, is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the device is to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Meridian Interbody is intended for use with supplemental fixation. Degenerative disc disease is defined as back pain of discogenic origin 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.

No-Profile Implants w/ Screws:
The SeaSpine Meridian System No-Profile Interbody, when used with Screws and with or without a No-Profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. Hyperlordotic sizes (greater than 20 degrees) are intended for use with supplemental fixation.

No-Profile Implants w/ Inline Fixation Anchors:
The SeaSpine Meridian System No-Profile Interbody, when used with Inline Fixation Anchors and a No Profile Locking Cover, is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The SeaSpine Meridian No-Profile Implants w/ Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:
The SeaSpine Meridian System Interbody assembled with the Anterior Plate, when used with Screws, an Anterior Plate Locking Cover, and with or without a Spin Plate, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. Hyperlordotic sizes (greater than 20 degrees) are intended for use 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*
K220711

Device Name
Meridian Anterior Plate System

Indications for Use *(Describe)*
The Meridian Anterior Plate System is indicated as additional support during fusion via an anterior or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

Type of Use *(Select one or both, as applicable)*

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

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510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

Address: 5770 Armada Drive, Carlsbad CA 92008
Phone number: (760) 216-5176
Fax number: (760) 683-6874

Contact Person: Jesse Albright, Associate Manager, Regulatory Affairs

Date Prepared: May 8, 2022

Device Name

Trade Name(s): SeaSpine Meridian System;
Meridian Anterior Plate System

Common Name(s): Intervertebral Body Fusion Device;
Spinal Intervertebral Body Fixation System

Classification Name(s): Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR 888.3080), Intervertebral Fusion Device With Integrated Fixation, Lumbar (21 CFR 888.3080);
Appliance, Fixation, Spinal Intervertebral Body (21 CFR 888.3060)

Class: II

Product Code(s): MAX, OVD;
KWQ

Legally Marketed Predicate Devices

510(k) Number	Product Code(s)	Trade Name	Manufacturer
Primary Predicate Device			
K201193	MAX, OVD	SeaSpine Meridian System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K210583	MAX, OVD	SeaSpine WaveForm A Interbody System	SeaSpine Orthopedics Corporation
K200885	KWQ	Meridian Anterior Plate System	SeaSpine Orthopedics Corporation

K072407	KWQ	Bodyform Thoracic Fixation System	SeaSpine Orthopedics Corporation (previously Theken Spine, LLC)

Device Description

The SeaSpine Meridian System featuring NanoMetalene® surface technology are single-use intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and/or titanium alloy (Ti-6Al-4V ELI per ASTM F136) markers for radiographic visualization and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67). NanoMetalene surface technology provides a microscopic roughened surface with nano-scale features. The spacers are available in a variety of footprints, heights, and lordotic configurations to accommodate variations in pathology and patient anatomy and include a central graft window for receiving autogenous bone graft and/or allogenic bone graft, composed of cancellous, cortical, and/or corticocancellous bone prior to implantation. The spacers are individually packaged in a double PETG/Tyvek tray configuration and gamma sterilized. The Meridian System spacers can be used in combination with Spin Plates, Anterior Plates, Anterior Plate Locking Covers, Screws, Inline Fixation Anchors, and/or No-Profile Locking Covers; these implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and are provided non-sterile.

The Meridian Anterior Plate System is comprised of single-use Anterior Plates, Screws, and Anterior Locking Covers, which are shared with the aforementioned Meridian SeaSpine System. The plates are offered in various heights and configurations, and they have no superior or inferior orientation requirement. The implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and are provided non-sterile.

Intended Use/Indications for Use

SeaSpine Meridian System

Interbody Device (IBD) Implants (i.e., interbody implants used alone):

The SeaSpine Meridian System with NanoMetalene® surface technology Interbody, when used with or without a Spin Plate, is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the device is to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine Meridian Interbody is intended for use with supplemental fixation. Degenerative disc disease is defined as back pain of discogenic origin 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.

No-Profile Implants w/ Screws:

The SeaSpine Meridian System No-Profile Interbody, when used with Screws and with or without a No-Profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to

fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. Hyperlordotic sizes (greater than 20 degrees) are intended for use with supplemental fixation.

No-Profile Implants w/ Inline Fixation Anchors:

The SeaSpine Meridian System No-Profile Interbody, when used with Inline Fixation Anchors and a No Profile Locking Cover, is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The SeaSpine Meridian No-Profile Implants w/ Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:

The SeaSpine Meridian System Interbody assembled with the Anterior Plate, when used with Screws, an Anterior Plate Locking Cover, and with or without a Spin Plate, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. Hyperlordotic sizes (greater than 20 degrees) are intended for use with supplemental fixation.

Meridian Anterior Plate System

The Meridian Anterior Plate System is indicated as additional support during fusion via an anterior or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

Summary of Technological Characteristics

The SeaSpine Meridian System and Meridian Anterior Plate System are identical or similar to the cited predicate devices in regard to components, device description, intended use/indications for use, technological characteristics (e.g., operating principle, design, materials, manufacturing, etc.) and performance (mechanical safety).

Non-Clinical Testing

Mechanical performance in axial compression and compression shear (ASTM F2077), compression bending and torsion (ASTM F1717), subsidence (ASTM F2267), wear evaluation (ASTM F1877), expulsion, and screw pushout testing was verified for the SeaSpine Meridian System and Meridian Anterior Plate System through engineering analysis.

Clinical Testing

Not applicable. The determination of substantial equivalence is not based on an assessment of clinical performance data.

Conclusions

The submitted data demonstrates that the SeaSpine Meridian System and Meridian Anterior Plate System are as safe, as effective, and perform at least as safely and effectively as the cited legally marketed predicates.