April 26, 2024

SeaSpine Orthopedics Corporation
Ms. Jesse Albright
Manager, Regulatory Affairs
5770 Armada Drive
Carlsbad, California 92008

Re: K240566
Trade/Device Name: Reef L Interbody System; WaveForm L Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: February 28, 2024
Received: February 29, 2024

Dear Ms. Albright:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240566

Device Name
Reef L Interbody System;
WaveForm L Interbody System

Indications for Use *(Describe)*

Reef L Interbody System

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

The Reef L Interbody System with NanoMetalene® surface technology is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

The Reef L Interbody System is intended for use as an adjunct to fusion in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1) for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two contiguous levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Reef L Interbody System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Reef L Interbody System is intended for use with supplemental fixation. Hyperlordotic sizes (greater than 20°) must be used with legally marketed anterior supplemental fixation.

TruProfile Interbody Implants (i.e., interbody implants used with TruProfile Plates):

The Reef L Interbody System assembled with the TruProfile Lateral Plate, when used with Screws, 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 L1 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). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft, allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The Reef L Interbody System assembled with the TruProfile Lateral Plate, when used with Screws, can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Reef L Interbody System assembled with the 1-Hole TruProfile Lateral Plate, when used with a single Screw, is intended for use with additional legally marketed anterior or posterior supplemental fixation.

WaveForm L Interbody System

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

The WaveForm L Interbody System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The

interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

The WaveForm L Interbody System is intended for use as an adjunct to fusion in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1) for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two contiguous levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The WaveForm L Interbody System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The WaveForm L Interbody System is intended for use with supplemental fixation. Hyperlordotic sizes (greater than 20°) must be used with legally marketed anterior supplemental fixation.

TruProfile Interbody Implants (i.e., interbody implants used with TruProfile Plates):
The WaveForm L Interbody System assembled with the TruProfile Lateral Plate, when used with Screws, 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 L1 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). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The WaveForm L Interbody System assembled with the TruProfile Lateral Plate, when used with Screws, can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The WaveForm L Interbody System assembled with the 1-Hole TruProfile Lateral Plate, when used with a single Screw, is intended for use with additional legally marketed anterior or posterior 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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K240556

510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

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

Contact person (primary): Jesse Albright, Manager, Regulatory Affairs

Date Prepared: April 5, 2024

Device Name

Trade Name(s): Reef L Interbody System
WaveForm L Interbody System

Common Name(s): Intervertebral Body Fusion Device

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), Intervertebral Fusion Device With Bone Graft, Thoracic (21 CFR 888.3080)

Class: 2

Product Code(s): MAX, OVD, PHM

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K210497	MAX, OVD	SeaSpine Regatta Lateral System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K213420	MAX, PHM	WaveForm L Interbody System	SeaSpine Orthopedics Corporation
K103111	MAX	Forza Spacer System	Orthofix, Inc.
K203714	MAX, OVD, PHM	CoRoent Thoracolumbar System, CoRoent XL Interfixated System	NuVasive, Inc.

Device Description

Reef L Interbody System

The Reef L Interbody System featuring NanoMetalene surface technology consists of lateral intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) markers for radiographic visualization and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67) that provides a microscopic roughened surface with nano-scale features. The interbody spacers are available in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy and include central graft windows for receiving autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The spacers are individually packaged and gamma sterilized.

The Reef L interbody spacers can be used alone with supplemental fixation or in combination with fixation implants (i.e., plates, screws, and locking covers) to create the TruProfile Interbody configuration. The fixation implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and provided non-sterile.

The system includes the associated non-sterile instruments that facilitate the placement, adjustment, and removal, if necessary, of the system implants as well as trays and caddies that may be used for storage, protection, and organization prior to and during the steam sterilization process for the non-sterile components.

WaveForm L Interbody System

The WaveForm L Interbody System consists of lateral intervertebral body fusion devices additively manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The interbody spacers are available in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy and include a central graft window for receiving autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The spacers are individually packaged and gamma sterilized.

The WaveForm L interbody spacers can be used alone with supplemental fixation or in combination with fixation implants (i.e., plates, screws, and locking covers) to create the TruProfile Interbody configuration. The fixation implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and provided non-sterile.

The system includes the associated non-sterile instruments that facilitate the placement, adjustment, and removal, if necessary, of the system implants as well as trays and caddies that may be used for storage, protection, and organization prior to and during the steam sterilization process for the non-sterile components.

Intended Use/Indications for Use

Reef L Interbody System

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

The Reef L Interbody System with NanoMetalene® surface technology is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

The Reef L Interbody System is intended for use as an adjunct to fusion in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1) for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two contiguous levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Reef L Interbody System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Reef L Interbody System is intended for use with supplemental fixation. Hyperlordotic sizes (greater than 20°) must be used with legally marketed anterior supplemental fixation.

TruProfile Interbody Implants (i.e., interbody implants used with TruProfile Plates):

The Reef L Interbody System assembled with the TruProfile Lateral Plate, when used with Screws, 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 L1 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). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft, allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The Reef L Interbody System assembled with the TruProfile Lateral Plate, when used with Screws, can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Reef L Interbody System assembled with the 1-Hole TruProfile Lateral Plate, when used with a single Screw, is intended for use with additional legally marketed anterior or posterior supplemental fixation.

WaveForm L Interbody System

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

The WaveForm L Interbody System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

The WaveForm L Interbody System is intended for use as an adjunct to fusion in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1) for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two contiguous levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The WaveForm L Interbody System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The WaveForm L Interbody System is intended for use with supplemental fixation. Hyperlordotic sizes (greater than 20°) must be used with legally marketed anterior supplemental fixation.

TruProfile Interbody Implants (i.e., interbody implants used with TruProfile Plates):

The WaveForm L Interbody System assembled with the TruProfile Lateral Plate, when used with Screws, 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 L1 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). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The WaveForm L Interbody System assembled with the TruProfile Lateral Plate, when used with Screws, can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The WaveForm L Interbody System assembled with the 1-Hole TruProfile Lateral Plate, when used with a single Screw, is intended for use with additional legally marketed anterior or posterior supplemental fixation.

Summary of Technological Characteristics

The Reef L Interbody System and WaveForm L Interbody System technological characteristics are substantially equivalent to the cited predicate devices. The equivalence determination was based on comparison of intended use/indications for use, operating principle, design and components, materials, biocompatibility, manufacturing, packaging, labeling, sterility, and non-clinical testing (i.e., mechanical performance).

Non-Clinical Testing

The Reef L Interbody System and WaveForm L Interbody System demonstrated substantially equivalent mechanical performance to the predicate systems through static and dynamic axial compression and compression-shear (ASTM F2077), subsidence (ASTM F2267), wear evaluation (ASTM F2077), and expulsion.

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 Reef L Interbody System and WaveForm L Interbody System are substantially equivalent to the cited legally marketed predicates.