June 20, 2024

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

Re: K241466
Trade/Device Name: Shoreline ACS Interbody System; Shoreline RT Interbody System; Regatta Lateral System; Reef L Interbody System; Reef TO/TA System; Meridian Interbody System; WaveForm C Interbody System; WaveForm L Interbody System; WaveForm TO Interbody System; WaveForm TA Interbody System; WaveForm A Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, PHM, OVE, ODP
Dated: May 23, 2024
Received: May 23, 2024

Dear Jesse 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241466

Device Name
Shoreline ACS Interbody System; Shoreline RT Interbody System; Regatta Lateral System; Reef L Interbody System; Reef TO/TA System; Meridian Interbody System; WaveForm C Interbody System; WaveForm L Interbody System; WaveForm TO Interbody System; WaveForm TA Interbody System; WaveForm A Interbody System

Indications for Use *(Describe)*

Shoreline ACS Interbody System

The Shoreline ACS Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. DDD is defined as discogenic 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) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When used as a standalone system, the Shoreline ACS Interbody System, which includes the TruProfile plates and No-profile spacer, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers. The Shoreline ACS interbody spacers with ≥ 20° lordosis are intended to be used with supplemental fixation.

When the Shoreline ACS Interbody (excluding the No-profile spacer) is used with supplemental fixation, such as anterior cervical plates, the Shoreline ACS Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

Shoreline RT Interbody System

The Shoreline RT Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. DDD is defined as discogenic 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) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When used as a standalone system, the Shoreline RT Interbody System, which includes the TruProfile plates, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers. The Shoreline RT interbody spacers with ≥ 20° lordosis are intended to be used with supplemental fixation.

When the Shoreline RT Interbody System is used with supplemental fixation, such as anterior cervical plates, the Shoreline RT Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

Regatta Lateral System

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

The Regatta Lateral 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 L2 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody 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 Regatta Lateral System is intended for use with supplemental fixation.

TruProfile Interbody Implants:
The Regatta Lateral 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 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 Regatta Lateral System assembled with the 1- hole TruProfile Lateral Plate, when used with Screws, is intended for use with supplemental fixation.

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.

Reef TO/TA System
When used as an intervertebral body fusion device, the Reef TO/TA System with NanoMetalene® surface technology is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with

degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

Meridian Interbody System
Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The 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. 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 should be skeletally mature and have had at least six (6) months of non-operative treatment. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The Meridian Interbody is intended for use with supplemental fixation.

No-Profile Interbody Implants with Screws:
The Meridian System 2-Hole and 3-Hole 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). 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 cancellous, cortical, and/or corticocancellous bone. The Meridian System 2-Hole and 3-Hole No-profile Interbody must be used with the maximum number of screws allowed. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

The Meridian System 4-Hole 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). 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. The Meridian System 4-Hole No-profile Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the 4-Hole No-profile Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

No-Profile Interbody Implants with Inline Fixation Anchors:
The 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). 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. The Meridian System No-profile Interbody with Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:
The Meridian System TruProfile 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). 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. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

WaveForm C Interbody System
The WaveForm C Interbody System are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. DDD is defined as discogenic 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) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When used as a standalone system, the WaveForm C Interbody System, which includes the 2,3,4-hole TruProfile plates and 2-hole No-profile interfixated spacer, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers.

When the WaveForm C Interbody System (excluding 2-hole No-profile interfixated spacer) is used with supplemental fixation, such as anterior cervical plates, the WaveForm C Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

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.

WaveForm TO Interbody System
When used as an intervertebral body fusion device, the system is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

WaveForm TA Interbody System
When used as an intervertebral body fusion device, the system is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

WaveForm A Interbody System
Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The WaveForm A System 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. 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 should be skeletally mature and have had at least six (6) months of non-operative treatment. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The WaveForm A System Interbody is intended for use with supplemental fixation.

No-profile Interbody Implants with Screws:
The WaveForm A System 2-Hole and 3-Hole 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). 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 cancellous, cortical, and/or corticocancellous bone. The WaveForm A System 2-Hole and 3-Hole No-profile Interbody must be used with the maximum number of screws allowed. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

The WaveForm A System 4-Hole 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). 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. The WaveForm A System 4-Hole No-profile Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the 4-Hole No-profile Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

No-profile Interbody Implants with Inline Fixation Anchors:
The WaveForm A System No-profile Interbody, when used with Inline Fixation Anchors and with 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). 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. The WaveForm A System No-profile Interbody with Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:
The WaveForm A System TruProfile 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). 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. Hyperlordotic sizes (greater than 20°) 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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510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

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Phone number: (760) 216-5176
Fax number: (760) 683-6874

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

Date Prepared: May 23, 2024

Device Name(s)

Trade Name(s):
Shoreline ACS Interbody System
Shoreline RT Interbody System
Regatta Lateral System
Reef L Interbody System
Reef TO/TA System
Meridian Interbody System
WaveForm C Interbody System
WaveForm L Interbody System
WaveForm TO Interbody System
WaveForm TA Interbody System
WaveForm A 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 Integrated Fixation, Cervical (21 CFR 888.3080), Intervertebral Fusion Device With Bone Graft, Cervical (21 CFR 888.3080), Intervertebral Fusion Device With Bone Graft, Thoracic (21 CFR 888.3080)

Class: 2

Product Code(s): MAX, OVD, PHM, OVE, ODP

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K210497	MAX, OVD	Regatta Lateral System, Reef TO/TA System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K240566	MAX, OVD, PHM	Reef L Interbody System, WaveForm L Interbody System	SeaSpine Orthopedics Corporation
K233694	MAX, OVD	Meridian Interbody System, WaveForm A Interbody System	SeaSpine Orthopedics Corporation
K233414	OVE, ODP	Shoreline ACS Interbody System, Shoreline RT Interbody System	SeaSpine Orthopedics Corporation
K213359	OVE, ODP	WaveForm C Interbody System	SeaSpine Orthopedics Corporation
K213420	MAX, PHM	WaveForm TO Interbody System, WaveForm TA Interbody System	SeaSpine Orthopedics Corporation

Device Description

Shoreline ACS Interbody System

The Shoreline ACS Interbody System featuring NanoMetalene surface technology consists of anterior cervical 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) that provides a microscopic roughened surface with nano-scale features. The interbody spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy. The spacers, which include a central graft window for receiving autogenous bone graft and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone, are individually packaged and gamma sterilized.

The Shoreline ACS Interbody System can be used with supplemental fixation, such as an anterior plate, or as a standalone construct in combination with non-sterile fixation implants (i.e., plates, bone screws, and locking covers) to create the TruProfile and No-profile configurations. The fixation implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136).

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.

Shoreline RT Interbody System

The Shoreline RT Interbody System featuring NanoMetalene surface technology consists of anterior cervical 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) that provides a microscopic roughened surface with nano-scale features. The interbody spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy. The spacers, which include a central graft window for receiving autogenous bone graft and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone, are individually packaged and gamma sterilized.

The Shoreline RT Interbody System can be used with supplemental fixation, such as an anterior plate, or as a standalone construct in combination with the Shoreline ACS Interbody System non-sterile fixation implants (i.e., plates, bone screws, and locking covers) to create the TruProfile configuration. The fixation implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136).

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.

Regatta Lateral System

The Regatta Lateral System featuring NanoMetalene surface technology consists of lateral lumbar intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (ASTM F2026) with from tantalum (per ASTM F560) radiographic markers and a one-micron thick surface layer of commercially pure titanium (per ASTM F67). 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 allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The spacers are individually packaged and gamma sterilized.

The Regatta Lateral 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.

Reef L Interbody System

The Reef L Interbody System featuring NanoMetalene surface technology consists of lateral lumbar 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.

Reef TO/TA System

The Reef TO/TA Interbody System featuring NanoMetalene surface technology consists of straight, rectangular-shaped (Reef TO) and curved, banana-shaped (Reef TA), posterior lumbar 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 a central graft window for receiving autogenous bone graft and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The spacers are individually packaged and gamma sterilized.

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.

Meridian Interbody System

The Meridian Interbody System featuring NanoMetalene surface technology consists of anterior lumbar intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and 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 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 and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The spacers are individually packaged and gamma sterilized.

The Meridian Interbody System spacers can be used alone with supplemental fixation or in combination with fixation implants to create the TruProfile and No-profile Interbody configurations. Fixation implants include Anterior Plates, Spin Plates, Screws, Inline Fixation Anchors, Anterior Plate Locking Covers, and No-profile Locking Covers, all of which 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 C Interbody System

The WaveForm C Interbody System consists of anterior cervical intervertebral body fusion devices additively manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The interbody spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy. The spacers, which include a central graft window for receiving autogenous bone graft and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone, are individually packaged and gamma sterilized.

The WaveForm C Interbody System can be used with supplemental fixation, such as an anterior plate, or as a standalone construct in combination with the Shoreline ACS Interbody System non-sterile fixation implants (i.e., plates, bone screws, and locking covers) to create the TruProfile and No-profile configurations. The fixation implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136).

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 lumbar 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.

WaveForm TO Interbody System

The WaveForm TO Interbody System consists of posterior lumbar intervertebral body fusion devices additively manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The straight, rectangular-shaped 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. The spacers are individually packaged and gamma sterilized.

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 TA Interbody System

The WaveForm TA Interbody System consists of posterior lumbar intervertebral body fusion devices additively manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The curved, banana-shaped 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. The spacers are individually packaged and gamma sterilized.

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 A Interbody System

The WaveForm A Interbody System consists of anterior lumbar intervertebral body fusion devices additively manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The interbody

spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy as well as with and without a sodium hydroxide (NaOH) surface treatment that provides a microscopic, roughened surface with nanoscale features. The interbody spacers, which include a central graft window for receiving autogenous and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone, are individually packaged and gamma sterilized.

The WaveForm A Interbody System spacers can be used alone with supplemental fixation or in combination with fixation implants to create the TruProfile and No-profile Interbody configurations. Fixation implants include Anterior Plates, Spin Plates, Screws, Inline Fixation Anchors, Anterior Plate Locking Covers, and No-profile Locking Covers, all of which 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

Shoreline ACS Interbody System

The Shoreline ACS Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. DDD is defined as discogenic 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) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When used as a standalone system, the Shoreline ACS Interbody System, which includes the TruProfile plates and No-profile spacer, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers. The Shoreline ACS interbody spacers with ≥ 20° lordosis are intended to be used with supplemental fixation.

When the Shoreline ACS Interbody (excluding the No-profile spacer) is used with supplemental fixation, such as anterior cervical plates, the Shoreline ACS Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

Shoreline RT Interbody System

The Shoreline RT Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. DDD is defined as discogenic 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) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When used as a standalone system, the Shoreline RT Interbody System, which includes the TruProfile plates, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers. The Shoreline RT interbody spacers with ≥ 20° lordosis are intended to be used with supplemental fixation.

When the Shoreline RT Interbody System is used with supplemental fixation, such as anterior cervical plates, the Shoreline RT Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

Regatta Lateral System

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

The Regatta Lateral 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 L2 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody 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 Regatta Lateral System is intended for use with supplemental fixation.

TruProfile Interbody Implants:

The Regatta Lateral 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 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 Regatta Lateral System assembled with the 1- hole TruProfile Lateral Plate, when used with Screws, is intended for use with supplemental fixation.

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.

Reef TO/TA System

When used as an intervertebral body fusion device, the Reef TO/TA System with NanoMetalene® surface technology is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

Meridian Interbody System

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

The 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. 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 should be skeletally mature and have had at least six (6) months of non-operative treatment. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The Meridian Interbody is intended for use with supplemental fixation.

No-Profile Interbody Implants with Screws:

The Meridian System 2-Hole and 3-Hole 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). 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 cancellous, cortical, and/or corticocancellous bone. The Meridian System 2-Hole and 3-Hole No-profile Interbody must be used with the maximum number of screws allowed. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

The Meridian System 4-Hole 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). 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. The Meridian System 4-Hole No-profile Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the 4-Hole No-profile Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

No-Profile Interbody Implants with Inline Fixation Anchors:

The 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). 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. The Meridian System No-profile Interbody with Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:

The Meridian System TruProfile 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). 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. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

WaveForm C Interbody System

The WaveForm C Interbody System are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. DDD is defined as discogenic 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) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When used as a standalone system, the WaveForm C Interbody System, which includes the 2,3,4-hole TruProfile plates and 2-hole No-profile interfixated spacer, is intended to be used as an

adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers.

When the WaveForm C Interbody System (excluding 2-hole No-profile interfixated spacer) is used with supplemental fixation, such as anterior cervical plates, the WaveForm C Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

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.

WaveForm TO Interbody System

When used as an intervertebral body fusion device, the system is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

WaveForm TA Interbody System

When used as an intervertebral body fusion device, the system is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

WaveForm A Interbody System

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

The WaveForm A System 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. 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 should be skeletally mature and have had at least six (6) months of non-operative treatment. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The WaveForm A System Interbody is intended for use with supplemental fixation.

No-profile Interbody Implants with Screws:

The WaveForm A System 2-Hole and 3-Hole 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). 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 cancellous, cortical, and/or corticocancellous bone. The WaveForm A System 2-Hole and 3-Hole No-profile Interbody must be used with the maximum number of screws allowed. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

The WaveForm A System 4-Hole 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). 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. The WaveForm A System 4-Hole No-profile Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the 4-Hole No-profile Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

No-profile Interbody Implants with Inline Fixation Anchors:

The WaveForm A System No-profile Interbody, when used with Inline Fixation Anchors and with 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). 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. The WaveForm A System No-profile Interbody with Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:

The WaveForm A System TruProfile 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). 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. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

Summary of Technological Characteristics

The Shoreline ACS Interbody System, Shoreline RT Interbody System, Regatta Lateral System, Reef L Interbody System, Reef TO/TA System, Meridian Interbody System, WaveForm C Interbody System, WaveForm L Interbody System, WaveForm TO Interbody System, WaveForm TA Interbody System, and WaveForm A Interbody System technological characteristics are substantially equivalent to the cited predicate devices. The subject and predicate systems are identical in regard to intended use/indications for use and technological characteristics, including operating principle, design and components, materials, manufacturing, biocompatibility, labeling, sterility, and non-clinical testing (i.e., mechanical performance). The subject systems differ from the predicate systems in regard to an additional sterile packaging configuration, which does not raise questions of safety and effectiveness as demonstrated through non-clinical testing.

Non-Clinical Testing

Testing performed for the additional sterile packaging configuration for the subject interbody spacer systems included cleaning (per ISO 19227), sterilization (per ISO 11137), and various package testing (per ISO 11607).

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 Shoreline ACS Interbody System, Shoreline RT Interbody System, Regatta Lateral System, Reef L Interbody System, Reef TO/TA System, Meridian Interbody System, WaveForm C Interbody System, WaveForm L Interbody System, WaveForm TO Interbody System, WaveForm TA Interbody System, and WaveForm A Interbody System are substantially equivalent to the cited legally marketed predicates.