July 1, 2026

SeaSpine Orthopedics Corporation
Kendal Moulton
Regulatory Affairs Specialist
5770 Armada Dr.
Carlsbad, California 92008

Re: K253420
Trade/Device Name: Admiral ACP System; Explorer TO System; Laminoplasty System; Manta Ray TDF Spacer; Meridian Interbody System; Meridian Anterior Plate System; Reef L Interbody System; Reef TO/TA System; Regatta Lateral System; Regatta Lateral Plate System; Shoreline ACS Interbody System; Shoreline Threaded TruProfile Plate; Shoreline RT Interbody System; Vu Mesh; WaveForm A Interbody System; WaveForm C Interbody System; WaveForm L Interbody System; WaveForm TA Interbody System; WaveForm TO Interbody System

Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 5, 2026
Received: June 5, 2026

Dear Kendal Moulton:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

BRENT SHOWALTER -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253420

Device Name
Admiral ACP System; Explorer TO System; Laminoplasty System; Manta Ray TDF Spacer; Meridian Interbody System; Meridian Anterior Plate System; Reef L Interbody System; Reef TO/ TA System; Regatta Lateral System; Regatta Lateral Plate System; Shoreline ACS Interbody System; Shoreline RT Interbody System; Shoreline Threaded TruProfile Plate System; Vu Mesh; WaveForm A Interbody System; WaveForm C Interbody System; WaveForm L Interbody System; WaveForm TA Interbody System; WaveForm TO Interbody System

Indications for Use *(Describe)*

Admiral ACP System
The Admiral ACP System is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion.

Explorer TO 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation.

Laminoplasty System
The SeaSpine Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) for laminoplasty procedures. The SeaSpine Laminoplasty System is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

Manta Ray TDF Spacer
The Manta Ray TDF Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-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.

The Manta Ray TDF Spacer is intended for use with autograft bone and/or allogenic 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 corticocancellous bone. The Meridian System 4-Hole Noprofile 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The Meridian 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

Meridian Anterior Plate System
The Meridian Anterior Plate System is indicated as additional support during fusion via an anterior or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

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 nonfusion 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation.

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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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.

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

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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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 Noprofile 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 Threaded TruProfile Plate
The Shoreline Threaded TruProfile Plate is intended for anterior cervical fixation (C2–T1) for the following indications:
• Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
• Spondylolisthesis,
• Trauma (i.e., fracture or dislocation),
• Spinal Stenosis,
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
• Tumor,
• Pseudarthrosis,
• Failed previous fusion.

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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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).

Vu•Mesh
The Vu•Mesh is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or otherwise unstable vertebral body due to tumor or trauma (i.e. fracture).

The Vu•Mesh system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. Bone graft material is recommended for packing into the interior opening of the device prior to implantation. The Vu•Mesh system is intended for use with supplemental internal spinal fixation systems.

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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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, are 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 2hole 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 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 nonfusion 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 cortical, cancellous, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and 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 nonfusion 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 cortical, cancellous, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR § 807.92, the following summary of information is provided:

A. Submitted by

Kendal Moulton
Regulatory Affairs Specialist
SeaSpine Orthopedics Corporation 5770
Armada Drive, Carlsbad, CA 92008
(760) 727-8399
Date Prepared: June 29th, 2026

B. Device Name

Tade or Proprietary Name:	*Admiral ACP System* *Explorer TO System* *Laminoplasty System* *Manta Ray TDF Spacer* *Meridian Interbody System* *Meridian Anterior Plate System* *Reef L Interbody System* *Reef TO/ TA System* *Regatta Lateral System* *Regatta Lateral Plate System* *Shoreline ACS Interbody System* *Shoreline RT Interbody System* *Shoreline Threaded TruProfile Plate System* *Vu Mesh* *WaveForm A Interbody System* *WaveForm C Interbody System* *WaveForm L Interbody System* *WaveForm TA Interbody System* *WaveForm TO Interbody System*
Common or Usual Name:	Appliance, Fixation, Spinal Intervertebral Body; Intervertebral Fusion Device with Bone Graft, Lumbar; Intervertebral Fusion Device with Bone Graft, Cervical
Classification Name(s):	Spinal Intervertebral Body Fixation Orthosis; Orthosis, Spine, Plate, Laminoplasty, Metal; Intervertebral Body Fusion Device
Device Class:	Class II
Regulation Number(s):	21 CFR 888.3060, 21 CFR 888.3050, 21 CFR 888.3080
Product Code(s):	KWQ, MQP; NQW; MAX, ODP, OVD, OVE, PHM

C. Legally Marketed Predicate Devices

510(k) Number	Product Code(s)	Trade Name	Manufacturer
Primary Predicate			
K232566	NKB, KWP, KWQ, PGM	NewPort Spinal System; Daytona Small Stature Spinal System; Malibu Spinal System; Mariner Pedicle Screw Systems: Mariner Outrigger Revision System; Mariner MIS Pedicle Screw System; Mariner Deformity System; Mariner RDX System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K240830	MAX, OVD, OVE, ODP, PHM	Reef TO/TA System; Regatta Lateral System; Explorer TO System; WaveForm C Interbody System; WaveForm TO Interbody System; WaveForm TA Interbody System; FORZA XP Expandable Spacer System; Shoreline ACS Interbody System; Shoreline RT Interbody System; Meridian Interbody System; WaveForm A Interbody System	Orthofix Medical Inc.
K240566	MAX, OVD	Reef L Interbody System; WaveForm L Interbody System	SeaSpine Orthopedics Corporation
K212139	KWQ	Admiral ACP System	SeaSpine Orthopedics Corporation
K150469	NQW	Integra Laminoplasty System	SeaSpine Orthopedics Corporation
K220296	ODP	Manta Ray TDF Spacer	SeaSpine Orthopedics Corporation
K220711	MAX, KWQ, OVD	Meridian Anterior Plate System	SeaSpine Orthopedics Corporation
K200885	KWQ	Regatta Lateral Plate System	SeaSpine Orthopedics Corporation
K211903	KWQ	Shoreline Threaded TruProfile Plate	SeaSpine Orthopedics Corporation

510(k) Number	Product Code(s)	Trade Name	Manufacturer
K070381	MQP	THEKEN VU MESH VBR SYSTEM	Theken Spine LLC

D. Device Description

Admiral ACP System

The Admiral ACP System implant components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The implantation of the Admiral ACP System is via an anterior surgical approach.

The Admiral ACP System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The Admiral plates include locking pins that cover the heads of the bone screws to reduce the potential for screw back-out. The locking pins come preassembled to the plate. Associated instruments are available to facilitate the implantation of the device. The Admiral ACP System implant components are made from titanium alloy such as described by ASTM F136. This material is not compatible with other metal alloys.

Explorer TO System

The ExplorerTM TO System is a lumbar intervertebral body fusion device used to act as a disc spacer and hold bone graft to promote fusion in the lumbar spine. The system consists of non-sterile implants manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136). The system is comprised of height expandable and lordotic expandable interbody spacers that include a large central graft window for receiving bone graft material. Both configurations are available in a range of lengths, widths, heights, and lordotic angles.

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.

Laminoplasty System

The SeaSpine Laminoplasty System consists of titanium 6Al-4V ELI alloy plates and screws that are attached to the lamina after a laminoplasty procedure. Implants are available in a range of sizes and shapes, as well as in various screw hole configurations to accommodate variations in patient anatomy. The system also includes instruments to assist with implantation and a tray for organization and storage.

Manta Ray TDF Spacer

The Manta Ray TDF Spacer is a cervical interbody spacer that engages the entire disc space, including the uncovertebral joints, during the fusion process. The interbody spacer is manufactured from polyetheretherketone (PEEK) (ASTM F2026), tantalum (ASTM F560), and NanoMetalene, which is a onemicron thick surface layer of commercially pure titanium (ASTM F67). NanoMetalene surface technology provides a microscopic roughened surface with

nanoscale features. Each spacer has a central graft window for receiving autograft and/or allogenic bone graft and is offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy. The Manta Ray TDF Spacer is intended for use with supplemental fixation.

The instruments provided with the Manta Ray TDF Spacer facilitate the placement, adjustment, and removal, if necessary, of the interbody spacer. The spacer is provided sterile packaged, whereas the instruments are provided in system-specific trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

Meridian Interbody System and Meridian Anterior Plate System
The Meridian™ Interbody System NanoMetalene™ surface technology consists of anterior lumbar intervertebral body fusion devices manufactured from polyetheretherketone (PEEKper ASTM F2026) with tantalum (per ASTM F560) and titanium alloy (Ti6Al-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 configurations to accommodate variations in pathology and patient anatomy and include a central graft window for receiving bone graft material. 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, including those from the Meridian Anterior Plate System, to create the TruProfile and Noprofile 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 Meridian Interbody System and Meridian Anterior Plate System include 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 TM featuring NanoMetaleneTM 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-6Al4V 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 Interbody Systems featuring NanoMetalene™ surface technology consist of posterior lumbar intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and/or titanium alloy (Ti-6Al4V ELI) (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 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 bone graft material. The spacers are individually packaged and gamma sterilized.

The systems include 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 tantalum (per ASTM F560) radiographic markers and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67) that provides a microscopic roughened surface with nanoscale 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 bone graft material. 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 nonsterile.

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 Plate System
The Regatta Lateral Plate Systems consists of varying sizes of plates and fixation options that accommodate lateral surgical approaches in the thoracic, lumbar, and sacral spine (T1-S1). Each plate is manufactured from titanium alloy per ASTM F136 and is designed to provide additional support during spinal fusion procedures.

Shoreline ACS Interbody System and Shoreline RT Interbody System
The Shoreline ACS Interbody System and Shoreline RT Interbody System, featuring NanoMetalene™ surface technology, consist of single-use anterior cervical intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and/or titanium alloy (Ti-6Al4V 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 bone graft material, are individually packaged in a double PETG/Tyvek tray configuration 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 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. Each TruProfile and No-profile construct must be used with the maximum number of screws allowed by the plate interface. The fixation implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136).

The Shoreline ACS and Shoreline RT Interbody Systems include 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 Threaded TruProfile Plate
The Shoreline Threaded TruProfile Plate is a spinal fixation system that consists of a variety of non-sterile, single-use plates, screws, and locking covers. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The TruProfile Plates include locking covers that cover the heads of the bone screws to reduce the potential for screw back-out. The TruProfile Plate implant components are made from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The TruProfile plate can be used with any compatible cervical spacer.

Vu Mesh
The Vu•Mesh VBR system is comprised of square footprint polymer cages with fenestrations axially and laterally. It includes toothed endplates, which are used in combination with optional spacer components to extend the range of the cage in smaller increments. The cages, spacers

and endplates can be assembled in a variety of combinations to fit each individual patient's pathology. The toothed endplates engage with the superior and inferior endplates of the neighboring vertebral bodies to resist rotation and migration. The Vu•Mesh cage may be used individually or in a pair depending on the surgical need, however, the device is always implanted with the mesh cage oriented vertically.

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. The interbody 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 A interbody 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-6Al4V 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 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 nonsterile.

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 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 bone graft material. 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 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 bone graft material. 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.

E. Indications for Use

Admiral ACP System

The Admiral ACP System is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion.

Explorer TO 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation.

Laminoplasty System

The SeaSpine Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) for laminoplasty procedures. The SeaSpine Laminoplasty System is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

Manta Ray TDF Spacer

The Manta Ray TDF Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-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.

The Manta Ray TDF Spacer is intended for use with autograft bone and/or allogenic 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 or a bone

void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 corticocancellous bone. The Meridian System 4-Hole Noprofile 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The Meridian 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

Meridian Anterior Plate System
The Meridian Anterior Plate System is indicated as additional support during fusion via an anterior or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

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 nonfusion 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation.

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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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.

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

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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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 Noprofile 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 Threaded TruProfile Plate
The Shoreline Threaded TruProfile Plate is intended for anterior cervical fixation (C2–T1) for the following indications:
- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Spinal Stenosis,
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- Tumor,
- Pseudarthrosis,
- Failed previous fusion.

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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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).

Vu•Mesh
The Vu•Mesh is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or otherwise unstable vertebral body due to tumor or trauma (i.e. fracture).

The Vu•Mesh system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. Bone graft material is recommended for packing into the interior opening of the device prior to implantation. The Vu•Mesh system is intended for use with supplemental internal spinal fixation systems.

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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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, are 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 2hole 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 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 nonfusion 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 cortical, cancellous, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and 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 nonfusion 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 cortical, cancellous, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation.

F. Technological Characteristics

The *Admiral ACP System, Explorer TO System, Laminoplasty System, Manta Ray TDF Spacer, Meridian Interbody System, Meridian Anterior Plate System, Reef L Interbody System, Reef TO/ TA System, Regatta Lateral System, Regatta Lateral Plate System, Shoreline ACS Interbody System, Shoreline RT Interbody System, Shoreline Threaded TruProfile Plate System, Vu Mesh, WaveForm A Interbody System, WaveForm C Interbody System, WaveForm L Interbody System, WaveForm TA Interbody System, and WaveForm TO Interbody System* are identical to the cited predicate devices in regard to components, device description, intended use/indications for use, technological characteristics (e.g., operating principle, design, materials, manufacturing, etc.) and performance (mechanical safety).

G. Performance Data

In accordance with the FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" the following testing was conducted:

- ASTM F2052-15 – Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment
- ASTM F2213-17 – Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment
- ASTM F2119-07 – Standard test method for evaluation of MR image artifacts from passive implants
- ASTM F2182-19E2 – Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging.

The results of these studies demonstrate that the subject *Admiral ACP System, Explorer TO System, Laminoplasty System, Manta Ray TDF Spacer, Meridian Interbody System, Meridian*

Anterior Plate System, Reef L Interbody System, Reef TO/ TA System, Regatta Lateral System, Regatta Lateral Plate System, Shoreline ACS Interbody System, Shoreline RT Interbody System, Shoreline Threaded TruProfile Plate System, Vu Mesh, WaveForm A Interbody System, WaveForm C Interbody System, WaveForm L Interbody System, WaveForm TA Interbody System, and WaveForm TO Interbody System are substantially equivalent to legally marketed devices.

H. Conclusion

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *Admiral ACP System, Explorer TO System, Laminoplasty System, Manta Ray TDF Spacer, Meridian Interbody System, Meridian Anterior Plate System, Reef L Interbody System, Reef TO/ TA System, Regatta Lateral System, Regatta Lateral Plate System, Shoreline ACS Interbody System, Shoreline RT Interbody System, Shoreline Threaded TruProfile Plate System, Vu Mesh, WaveForm A Interbody System, WaveForm C Interbody System, WaveForm L Interbody System, WaveForm TA Interbody System, and WaveForm TO Interbody System* have been shown to be substantially equivalent to the legally marketed predicate devices.