January 12, 2024

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

Re: K233694
Trade/Device Name: Meridian Interbody System; WaveForm A Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: November 16, 2023
Received: November 17, 2023

Dear Jesse Albright:

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

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

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

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

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

Sincerely,

Katherine D. Kavlock -S

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

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K233694

Device Name
Meridian Interbody System
WaveForm A Interbody System

Indications for Use *(Describe)*

Meridian Interbody System

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

The Meridian System with NanoMetalene® surface technology Interbody, when used with or without a Spin Plate, is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The Meridian Interbody is intended for use with supplemental fixation.

No-Profile Interbody Implants with Screws:

The Meridian System 2-Hole and 3-Hole No-profile Interbody, when used with Screws and with or without a No-profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed cancellous, cortical, and/or corticocancellous bone. The Meridian System 2-Hole and 3-Hole No-profile Interbody must be used with the maximum number of screws allowed. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

The Meridian System 4-Hole No-profile Interbody, when used with Screws and with or without a No-profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The Meridian System 4-Hole No-profile Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the 4-Hole No-profile Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

No-Profile Interbody Implants with Inline Fixation Anchors:

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

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

WaveForm A Interbody System
Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The WaveForm A System Interbody, when used with or without a Spin Plate, is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The WaveForm A System Interbody is intended for use with supplemental fixation.

No-profile Interbody Implants with Screws:
The WaveForm A System 2-Hole and 3-Hole No-profile Interbody, when used with Screws and with or without a No-profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed cancellous, cortical, and/or corticocancellous bone. The WaveForm A System 2-Hole and 3-Hole No-profile Interbody must be used with the maximum number of screws allowed. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

The WaveForm A System 4-Hole No-profile Interbody, when used with Screws and with or without a No-profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The WaveForm A System 4-Hole No-profile Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the 4-Hole No-profile Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

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

TruProfile Interbody Implants:

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

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

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Contact person: Jesse Albright, Manager, Regulatory Affairs

Date Prepared: January 9, 2024

Device Name

Trade Name(s): Meridian Interbody System
WaveForm A Interbody System

Common Name(s): Intervertebral Body Fusion Device

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

Class: 2

Product Code(s): MAX, OVD

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K220711	MAX, OVD	Meridian Interbody System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K222732	MAX, OVD	WaveForm A Interbody System	SeaSpine Orthopedics Corporation
K121211	OVD	Vu aPOD Intervertebral Body Fusion Device	SeaSpine Orthopedics Corporation
K201671	OVD	A-Link Z	Acuity Surgical Devices, LLC

Device Description

Meridian Interbody System

The Meridian Interbody System featuring NanoMetalene® surface technology consists of anterior intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and titanium alloy (Ti-6Al-4V ELI per ASTM F136) markers for radiographic visualization and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67). NanoMetalene surface technology provides a microscopic roughened surface with nano-scale features. The interbody spacers are available in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy and include a central graft window for receiving autogenous and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The spacers are individually packaged and gamma sterilized.

The Meridian Interbody System spacers can be used alone with supplemental fixation or in combination with fixation implants to create the TruProfile and No-profile Interbody configurations. Fixation implants include Anterior Plates, Spin Plates, Screws, Inline Fixation Anchors, Anterior Plate Locking Covers, and No-profile Locking Covers, all of which are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and provided non-sterile.

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

WaveForm A Interbody System

The WaveForm A Interbody System consists of anterior intervertebral body fusion devices additively manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The interbody spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy as well as with and without a sodium hydroxide (NaOH) surface treatment that provides a microscopic, roughened surface with nanoscale features. The interbody spacers, which include a central graft window for receiving autogenous and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone, are individually packaged and gamma sterilized.

The WaveForm A Interbody System spacers can be used alone with supplemental fixation or in combination with fixation implants to create the TruProfile and No-profile Interbody configurations. Fixation implants include Anterior Plates, Spin Plates, Screws, Inline Fixation Anchors, Anterior Plate Locking Covers, and No-profile Locking Covers, all of which are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and provided non-sterile.

The system includes the associated non-sterile instruments that facilitate the placement, adjustment, and removal, if necessary, of the system implants as well as trays and caddies that

may be used for storage, protection, and organization prior to and during the steam sterilization process for the non-sterile components.

Intended Use/Indications for Use

Meridian Interbody System

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

The Meridian System with NanoMetalene® surface technology Interbody, when used with or without a Spin Plate, is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The Meridian Interbody is intended for use with supplemental fixation.

No-Profile Interbody Implants with Screws:

The Meridian System 2-Hole and 3-Hole No-profile Interbody, when used with Screws and with or without a No-profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed cancellous, cortical, and/or corticocancellous bone. The Meridian System 2-Hole and 3-Hole No-profile Interbody must be used with the maximum number of screws allowed. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

The Meridian System 4-Hole No-profile Interbody, when used with Screws and with or without a No-profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The Meridian System 4-Hole No-profile Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the 4-Hole No-profile Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

No-Profile Interbody Implants with Inline Fixation Anchors:

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

TruProfile Interbody Implants:

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

WaveForm A Interbody System

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

The WaveForm A System Interbody, when used with or without a Spin Plate, is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The WaveForm A System Interbody is intended for use with supplemental fixation.

No-profile Interbody Implants with Screws:

The WaveForm A System 2-Hole and 3-Hole No-profile Interbody, when used with Screws and with or without a No-profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may

also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed cancellous, cortical, and/or corticocancellous bone. The WaveForm A System 2-Hole and 3-Hole No-profile Interbody must be used with the maximum number of screws allowed. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

The WaveForm A System 4-Hole No-profile Interbody, when used with Screws and with or without a No-profile Locking Cover, is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The WaveForm A System 4-Hole No-profile Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the 4-Hole No-profile Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

No-profile Interbody Implants with Inline Fixation Anchors:

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

TruProfile Interbody Implants:

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

and/or corticocancellous bone. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

Summary of Technological Characteristics

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

Non-Clinical Testing

The Meridian Interbody System and WaveForm A Interbody System demonstrated substantially equivalent mechanical performance to the predicate systems through static and dynamic axial compression and compression shear (ASTM F2077), subsidence (ASTM F2267), wear evaluation (ASTM F1877), screw pushout, and expulsion.

Clinical Testing

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

Conclusions

The submitted data demonstrates that the Meridian Interbody System and WaveForm A Interbody System are substantially equivalent to the cited legally marketed predicates.