June 20, 2024

Orthofix Medical Inc.
% Mr. Justin Eggleton
VP, Head of Musculoskeletal Regulatory Affairs
803 7th Street NW, 3rd Floor,
Washington, DC 20001

Re: K240830
Trade/Device Name: 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
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD, OVE, ODP, PHM
Dated: March 26, 2024
Received: March 26, 2024

Dear Mr. Eggleton:

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,

Stephanie Smith -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)*
K240830

Device Name
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 and RT Interbody System, Meridian Interbody System, WaveForm A Interbody System

Indications for Use *(Describe)*

Reef TO/TA System

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

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.

WaveForm C Interbody System
The WaveForm C Interbody System are interbody fusion devices intended for use in skeletally mature patient 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, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers.
When the WaveForm C Interbody (excluding 2-hole No-profile interfixated spacer) is used with supplemental fixation, such as anterior cervical plates, the WaveForm C Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

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

FORZA XP Expandable Spacer
FORZA XP Expandable Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).
FORZA XP Expandable Spacer System is intended for use with autograft and/or allograft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation.
Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with FORZA XP Expandable Spacer System.

Shoreline ACS and RT Interbody System

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

Shoreline RT Interbody System:
The Shoreline RT Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone 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).

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

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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# *K240830 - 510(k) Summary*

| | |
|---|---|
| **Device Trade Name:** | Reef TO/TA System<br>Regatta Lateral System<br>Explorer TO System<br>WaveForm C Interbody System<br>WaveForm TO Interbody System<br>WaveForm TA Interbody System<br>FORZA XP Expandable Spacer System<br>Shoreline ACS and RT Interbody System<br>Meridian Interbody System<br>WaveForm A Interbody System |
| **Manufacturer:** | SeaSpine Orthopedics Corporation<br>5770 Armada Drive<br>Carlsbad, CA 92008<br><br>Orthofix US LLC<br>3451 Plano Parkway<br>Lewisville, TX 75056 |
| **Contact:** | Jesse Albright<br>Manager, Regulatory Affairs<br>815-342-2428 |
| **Prepared by:** | Justin Eggleton, Vice President, Head of Musculoskeletal Regulatory Affairs<br>MCRA, LLC<br>803 7th Street, NW, 3rd Floor<br>Washington, DC 20001<br>jeggleton@mcra.com<br>Office: 202.552.5800 |
| **Date Prepared:** | May 2, 2024 |
| **Classifications:** | 21 CFR §888.3080; Intervertebral body fusion device |
| **Class:** | II |
| **Product Codes:** | MAX, OVD, OVE, ODP, PHM |

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|---|---|
| **Primary Predicate:** | VariLift®-C Interbody Fusion System, Wenzel Spine, Inc., K231076<br>NuVasive Cohere ALIF System Intervertebral Body Fusion Device, NuVasive Incorporated, K221751<br>NuVasive Brigade System, NuVasive Incorporated, K203714<br>NuVasive CoRoent Small Interlock System, NuVasive Incorporated, K231735 |
| **Additional Predicate:** | Reef TO/TA System, SeaSpine, K210497<br>Regatta Lateral System, SeaSpine, K210497<br>Explorer TO System, SeaSpine, K212540<br>WaveForm C Interbody System, SeaSpine, K212904/K213359<br>WaveForm TO Interbody System, SeaSpine, K213420<br>WaveForm TA Interbody System, SeaSpine, K213420<br>FORZA XP Expandable Spacer System, Orthofix, K213951<br>Shoreline ACS and RT Interbody System, SeaSpine, K233414<br>Meridian Interbody System, SeaSpine, K233694<br>WaveForm A Interbody System, SeaSpine, K233694 |

**Indications For Use:**

***Reef TO/TA System***

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

***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.

***WaveForm C Interbody System***

The WaveForm C Interbody System are interbody fusion devices intended for use in skeletally mature patient 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, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers.

When the WaveForm C Interbody (excluding 2-hole No-profile interfixated spacer) is used with supplemental fixation, such as anterior cervical plates, the WaveForm C Interbody System is

intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

***WaveForm TO Interbody System***

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

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

***FORZA XP Expandable Spacer***

FORZA XP Expandable Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).

FORZA XP Expandable Spacer System is intended for use with autograft and/or allograft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with FORZA XP Expandable Spacer System.

***Shoreline ACS and RT Interbody System***

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

**Shoreline RT Interbody System:**

The Shoreline RT Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone 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).

***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 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 or a bone void filler as cleared by FDA for use in intervertebral body fusion

to facilitate fusion. 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 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 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.

**Device Description:**
There were no changes to the technological characteristics of the subject devices since the prior submissions. The subject 510(k) is specific to the indications for use only.

**Reef TO/TA System**

The Reef TO/TA Interbody System featuring NanoMetalene® surface technology consists of straight, rectangular-shaped (Reef TO) and curved, banana-shaped (Reef TA), posterior lumbar intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) markers for radiographic visualization and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67) that provides a microscopic roughened surface with nano-scale features. The interbody spacers are available in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy and include a central graft window for receiving autogenous bone graft and/or 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 system includes the associated non-sterile instruments that facilitate the placement, adjustment, and removal, if necessary, of the system implants as well as trays and caddies that may be used for storage, protection, and organization prior to and during the steam sterilization process for the non-sterile components.

**Regatta Lateral System**

The Regatta Lateral System featuring NanoMetalene surface technology consists of lateral lumbar intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (ASTM F2026) with from tantalum (per ASTM F560) radiographic markers and a one-micron thick surface layer of commercially pure titanium (per ASTM F67). The interbody spacers are available in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy and include central graft windows for receiving autogenous bone graft and/or 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. The spacers are individually packaged and gamma sterilized.

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

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

**Explorer TO System**

The Explorer 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, and 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.

**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 material, are individually packaged and gamma sterilized.

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

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

**WaveForm TO Interbody System**

The WaveForm TO Interbody System consists of posterior lumbar intervertebral body fusion devices additively manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The straight, rectangular-shaped interbody spacers are available in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy and include a central graft window for receiving autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone 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 system includes the associated non-sterile instruments that facilitate the placement, adjustment, and removal, if necessary, of the system implants as well as trays and caddies that may be used for storage, protection, and organization prior to and during the steam sterilization process for the non-sterile components.

**WaveForm TA Interbody System**

The WaveForm TA Interbody System consists of posterior lumbar intervertebral body fusion devices additively manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The curved, banana-shaped interbody spacers are available in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy and include a central graft window for receiving autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone 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 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.

**FORZA XP Expandable Spacer System**
The FORZA XP Expandable Spacer System is comprised of an assortment of single-use spacers made from titanium alloy and PEEK polymer with height expansion capability. The implants feature a bulleted nose for ease of insertion and anti-migration ripples on both the inferior and superior surfaces to provide increased stability and help prevent anterior/posterior movement of the device.

FORZA XP spacers are provided in both sterile and non-sterile configurations. The implants are offered in non-lordotic, lordotic, and hyperlordotic configurations to help restore the natural curvature of the spine. The implants can be used in single placement or pairs with typical approaches being transforaminal lumbar interbody fusion (TLIF) and posterior lumbar interbody fusion (PLIF).

The FORZA XP Expandable Spacer System is not intended to be used as a stand-alone device and must be used with a supplemental fixation system.

**Shoreline ACS Interbody System**
The Shoreline ACS Interbody System featuring NanoMetalene® surface technology consists of anterior cervical intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and/or titanium alloy (Ti-6Al-4V ELI per ASTM F136) markers for radiographic visualization and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67) that provides a microscopic roughened surface with nano-scale features. The interbody spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy. The spacers, which include a central graft window for receiving autogenous bone graft and/or allogenic bone graft material or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation, are individually packaged and gamma sterilized.

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

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

for the non-sterile components.

**Shoreline RT Interbody System**
The Shoreline RT Interbody System featuring NanoMetalene® surface technology consists of anterior cervical intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and/or titanium alloy (Ti-6Al-4V ELI per ASTM F136) markers for radiographic visualization and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67) that provides a microscopic roughened surface with nano-scale features. The interbody spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy. The spacers, which include a central graft window for receiving autogenous bone graft and/or allogenic bone graft material or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation, are individually packaged and gamma sterilized.

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

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

**Meridian Interbody System**
The Meridian Interbody System featuring NanoMetalene® surface technology consists of anterior lumbar intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and titanium alloy (Ti-6Al-4V ELI per ASTM F136) markers for radiographic visualization and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67). NanoMetalene surface technology provides a microscopic roughened surface with nano-scale features. The interbody spacers are available in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy and include a central graft window for receiving autogenous and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation. 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 lumbar intervertebral body fusion devices additively manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The interbody spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy as well as with and without a sodium hydroxide (NaOH) surface treatment that provides a microscopic, roughened surface with nanoscale features. The interbody spacers, which include a central graft window for receiving autogenous and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental fixation, 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.

**Summary of Technological Characteristics:**
The subject devices and predicate devices are identical in all respects except for the indications for use (as described above).

**Performance Testing Summary:**
The purpose of this submission is to expand the indications for use of the Orthofix Medical Inc. Interbody System devices to include use in the use of a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

Because the subject device is identical to the previously cleared primary predicate devices (K231076, K221751, K203714, K231735), it was determined that existing testing data is adequate to support the expanded indications proposed in the current submission.

**Conclusion:**
The subject devices and predicate devices are identical in all respects except for the indications for use. The data included in this submission demonstrate substantial equivalence to the predicate

devices listed above. The subject Interbody Systems are as safe, as effective, and perform as well as, or better, than the predicate devices.