November 7, 2022

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

Re: K222732
Trade/Device Name: 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: September 7, 2022
Received: September 9, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K222732

Device Name
WaveForm A Interbody System

Indications for Use *(Describe)*
Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The SeaSpine 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. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the device is to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine WaveForm A Interbody is intended for use with supplemental fixation. Degenerative disc disease is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment.

No-profile Implants w/ Screws:
The SeaSpine WaveForm A System 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). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. Hyperlordotic sizes (greater than 20 degrees) are intended for use with supplemental fixation.

No-profile Implants w/ Inline Fixation Anchors:
The SeaSpine 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). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The SeaSpine WaveForm A Noprofile Implants w/ Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:
The SeaSpine WaveForm A System 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). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. Hyperlordotic sizes (greater than 20 degrees) 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

Address: 5770 Armada Drive, Carlsbad, CA 92008
Phone number: (760) 216-5176
Fax number: (760) 683-6874

Contact Person: Jesse Albright, Associate Manager, Regulatory Affairs

Date Prepared: September 7, 2022

Device Name

Trade Name: WaveForm A Interbody System

Common Name: Intervertebral Body Fusion Device

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

Product Code(s): MAX, OVD

Device Class: 2

Legally Marketed Predicate Devices

510(k) Number	Product Code(s)	Trade Name(s)	Manufacturer
Primary Predicate Device			
K210583	MAX, OVD	WaveForm A Interbody System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K220711	MAX, OVD	Meridian System	SeaSpine Orthopedics Corporation
K213420	MAX, PHM	WaveForm L Interbody System, WaveForm TO Interbody System, WaveForm TA Interbody System	SeaSpine Orthopedics Corporation

Device Description

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 configurations 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 spacers, which include a central graft window for receiving autogenous bone graft and/or allogenic bone graft material, are individually packaged in a double PETG/Tyvek tray configuration and gamma sterilized.

The WaveForm A Interbody 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

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

The SeaSpine 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. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the device is to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The SeaSpine WaveForm A Interbody is intended for use with supplemental fixation. Degenerative disc disease is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment.

No-profile Implants w/ Screws:

The SeaSpine WaveForm A System 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). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen

of at least six (6) months of non-operative treatment prior to being treated with the device. Hyperlordotic sizes (greater than 20 degrees) are intended for use with supplemental fixation.

No-profile Implants w/ Inline Fixation Anchors:

The SeaSpine 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). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The SeaSpine WaveForm A No-profile Implants w/ Inline Fixation Anchors is intended for use with supplemental fixation.

TruProfile Interbody Implants:

The SeaSpine WaveForm A System 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). The interior of the spacer component may be packed with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. Hyperlordotic sizes (greater than 20 degrees) are intended for use with supplemental fixation.

Summary of Technological Characteristics

The WaveForm A Interbody System is identical or similar to the cited predicate systems in regard to intended use/indications for use, device description, technological characteristics (e.g., operating principle, design, components, materials, manufacturing, labeling, sterility, etc.), and non-clinical performance (i.e., mechanical testing).

Non-Clinical Testing

The WaveForm A Interbody System demonstrated substantially equivalent mechanical performance to the predicate systems through axial compression and compression-shear (ASTM F2077), wear evaluation (ASTM F1877), and subsidence (ASTM F2267) testing.

Clinical Testing

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

Conclusions

The submitted data demonstrate that the WaveForm A Interbody System is substantially equivalent to the cited legally marketed predicates.