June 2, 2021

SeaSpine Orthopedics Corporation
Aly Alvarez
Associate Manager, Regulatory Affairs
5770 Armada Drive
Carlsbad, California 92008

Re: K210583
Trade/Device Name: SeaSpine 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: May 3, 2021
Received: May 5, 2021

Dear Aly Alvarez:

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,

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)*
K210583

Device Name
SeaSpine WaveForm™ A Interbody System

Indications for Use *(Describe)*

Interbody Device (IBD) Implants (i.e., interbody implants used alone):
The SeaSpine WaveForm A System Interbody 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 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 (25 and 30 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 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 Interbody assembled with the Anterior Plate, when used with Screws and an Anterior Plate 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 (25 and 30 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
Phone number: (619) 884-4342 (Aly) or 760-271-6804 (Alicia)
Fax number: (760) 683-6874

Contact person: Aly Alvarez, Associate Manager, Regulatory Affairs
Additional contact: Alicia McArthur, Regulatory Affairs Specialist, Regulatory Affairs

Date Prepared: May 4, 2021

Device Name

Trade Name:	SeaSpine WaveForm™ A Interbody System
Device Classification Regulation:	888.3080
Common Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral body fusion device with bone graft, lumbar; Intervertebral body fusion device with integrated fixation, lumbar
Class:	II
Product Code:	MAX, OVD

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K201193	MAX, OVD	SeaSpine Meridian System	SeaSpine Orthopedics Corporation
Additional Predicate Device			
K101310	OVD	SeaSpine Vu a•POD Intervertebral Body Fusion Device	SeaSpine Orthopedics Corporation (previously Theken Spine)
Additional Predicate Device			
K201755	MAX	SeaSpine WaveForm TO System	SeaSpine Orthopedics Corporation

Device Description

The Seaspine WaveForm A System are additively manufactured intervertebral fusion devices with large central graft windows which are packed with autogenous bone graft and/or allogenic bone graft, composed of cancellous, cortical, and/or corticocancellous bone prior to implantation. The implants are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001 and are provided sterile-packed. The WaveForm A interbodies have the ability to accept an anterior faceplate and offer various configurations that can be used with bone screws or inline fixation anchors, locking covers and an optional spin plate. The instruments included with the system facilitate the placement and adjustment of the interbody spacers, and removal if necessary. The instruments are placed in system-specific tray components for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/Indications for Use

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

The SeaSpine WaveForm A System Interbody 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 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 (25 and 30 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 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 Interbody assembled with the Anterior Plate, when used with Screws and an Anterior Plate 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 (25 and 30 degrees) are intended for use with supplemental fixation.

Summary of Technological Characteristics

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

The implants are used to treat the same conditions, have essentially the same precautions and contraindications for use, and represent a basic design concept in terms of safety and effectiveness, and differ only in design details and not functionality.

Non-Clinical Testing

Mechanical Performance in compression and compression-shear (ASTM F2077), subsidence (ASTM F2267), wear testing (F1877), expulsion, and static screw push out was performed. Packaging, shipping and sterilization tests were also conducted to validate a Sterility Assurance Level (SAL) of 10 -6 and ensure maintenance of a sterile barrier. Bacterial Endotoxin (BET) was conducted in accordance with ANSI/AAMI ST- 72:2011. The SeaSpine WaveForm A System has demonstrated equivalent mechanical performance to the predicate system in accordance with these requirements.

Conclusions

The submitted data demonstrates that the SeaSpine WaveForm A System performs at least as safely and effectively as the cited legally marketed predicate.