December 15, 2020

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

Re: K201755
Trade/Device Name: WaveForm™ L Interbody System, WaveForm™ TO Interbody System, WaveForm™ TA Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: November 11, 2020
Received: November 12, 2020

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201755

Device Name

SeaSpine WaveForm™ L Interbody System

Indications for Use *(Describe)*

The SeaSpine WaveForm™ L System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cortical, cancellous 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™ L System is intended for use as an adjunct to fusion in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The SeaSpine WaveForm™ L System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

The SeaSpine WaveForm™ L System is 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201755

Device Name

SeaSpine WaveForm™ TO Interbody System

Indications for Use *(Describe)*

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

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201755

Device Name
SeaSpine WaveForm™ TA Interbody System

Indications for Use *(Describe)*

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

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

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

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510(k) Summary

K201755

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

Address: 5770 Armada Drive, Carlsbad CA
Phone number: (619) 884-4342
Fax number: (760) 683-6874

Contact person: Aly Alvarez, Assoc. Manager

Date Prepared: June 25, 2020

Device Name

Trade Name:
1. SeaSpine WaveForm™ L Interbody System
2. SeaSpine WaveForm™ TO Interbody System
3. SeaSpine WaveForm™ TA Interbody System

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)

Class: II

Product Code: MAX, PHM

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K082310	MAX, MQP	SeaSpine Spacer System – Pacifica	SeaSpine Orthopedics Corporation (formerly Theken Spine)
Additional Predicate Devices			
K163230	MAX, PHM	NuVasive Modulus XLIF Interbody System	NuVasive, Incorporated

K181079	MAX	SeaSpine Regatta Lateral System	SeaSpine Orthopedics Corporation
K192132	MAX	SeaSpine Beachside System (TLIF-O & TLIF-A)	SeaSpine Orthopedics Corporation

Device Description

The Seaspine WaveForm™ Lumbar Systems 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. WaveForm™ Lumbar System includes 3 different implants:

- A straight, rectangular-shaped cage, intended for lateral surgical placements, and referred to as WaveForm™ L
- A straight, rectangular-shaped cage, intended for posterior and transforaminal surgical placements, and referred to as WaveForm™ TO, and
- A curved, banana-shaped cage, intended for transforaminal surgical placements, and referred to as WaveForm™ TA, and

The implants are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001 and are provided sterile-packed. The instruments included with each 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

WaveForm™ L Interbody System

The SeaSpine WaveForm™ L System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cortical cancellous 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™ L System is intended for use as an adjunct to fusion in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The SeaSpine WaveForm™ L System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

The SeaSpine WaveForm™ L System is intended for use with supplemental fixation.

WaveForm™ TO Interbody System

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

Summary of Technological Characteristics

The SeaSpine WaveForm™ Lumbar Systems are 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

The SeaSpine WaveForm™ Lumbar Systems have demonstrated equivalent mechanical performance to the predicate system in accordance with requirements outlined in ASTM F2077, ASTM F2267, and ASTM F1877.

Conclusions

The submitted data demonstrates that the SeaSpine WaveForm™ Lumbar Systems perform at least as safely and effectively as the cited legally marketed predicate.