September 18, 2020

SeaSpine Orthopedics Corporation
Aly Alvarez
Sr. Specialist, Regulatory Affairs
5770 Armada Drive
Carlsbad, California 92008

Re: K201073
Trade/Device Name: SeaSpine WaveForm™ C Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: August 18, 2020
Received: August 19, 2020

Dear Ms. 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)*
K201073

Device Name
WaveForm™ C Interbody System

Indications for Use *(Describe)*
Intended Use/Indications for Use
The SeaSpine WaveForm™ C Interbody System are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two contiguous levels, depending on the system. 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.

When used as a standalone system, the WaveForm™ C Interbody System, including the Low Profile and No-Profile standalone interfixated spacer, is intended to be used as an adjunct to spinal fusion procedures at a single level of the cervical spine (C2-T1), and must be used with bone screw fixation and locking covers.

When 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 one or two contiguous levels of the cervical spine (C2-T1).

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
Fax number: (760) 683-6874

Contact person: Aly Alvarez, Sr. Regulatory Affairs Specialist

Date Prepared: April 21, 2020

Device Name

Trade Name: SeaSpine WaveForm™ C Interbody System

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral fusion device with bone graft, cervical (21 CFR 888.3080)

Class: II

Product Code: OVE, ODP

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K161081	OVE	SeaSpine Shoreline ACS – Anterior Cervical Standalone System	SeaSpine Orthopedics Corporation
Additional Predicate Devices			
K151939	OVE, ODP, KWQ	Coalition Spacers	Globus Medical, Inc.
K173115	ODP, KWQ, OVE	Coalition Spacers	Globus Medical, Inc.
K183083	ODP, OVE	Shoreline Cervical Interbody RT System	SeaSpine Orthopedics Corporation

Device Description

The SeaSpine WaveForm™ C Interbody System is an additively manufactured implant comprised of cervical spacers. Each spacer consists of 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 WaveForm™ C Interbody System offers spacers in low profile (TruProfile) and no profile versions and are manufactured from Ti-6Al-4V titanium alloy per ASTM F3001.

The WaveForm™ C Interbody System can be used with supplemental fixation, such as an anterior plate or as a standalone construct to be used with bone screw fixation and locking cover. The instruments included with the system facilitate the placement and adjustment of the interbody spacer, and removal if necessary. The instruments are placed in system-specific trays for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/Indications for Use

The SeaSpine WaveForm™ C Interbody System are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two contiguous levels, depending on the system. 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.

When used as a standalone system, the WaveForm™ C Interbody System, including the Low Profile and No-Profile standalone interfixated spacer, is intended to be used as an adjunct to spinal fusion procedures at a single level of the cervical spine (C2-T1), and must be used with bone screw fixation and locking covers.

When 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 one or two contiguous levels of the cervical spine (C2-T1).

Summary of Technological Characteristics

The WaveForm™ C Interbody System and predicate devices have the same operational principle; they act as a disc spacer and hold bone graft. The WaveForm™ C Interbody System is substantially equivalent to the cited predicate devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

The subject and predicate devices are based on the following similar technological elements:

- Implant Spacer Heights
- Spacer Footprints
- Spacer Lordotic Angles
- Screw Sizes and Lengths

Non-Clinical Testing

The WaveForm™ C Interbody System has been testing in accordance with requirements outlined in ASTM F2077, F2267, and F1877.

Conclusion

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