September 14, 2020

SeaSpine® Orthopedics Corporation
Ms. Jesse Albright
Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K201646
Trade/Device Name: Shoreline ACS (Anterior Cervical System)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: June 16, 2020
Received: June 17, 2020

Dear Ms. 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,

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)*
K201646

Device Name
Shoreline ACS (Anterior Cervical System)

Indications for Use *(Describe)*
The Shoreline ACS (Anterior Cervical System) are interbody fusion devices intended for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The Shoreline ACS implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous, cortical, and / or corticocancellous bone and implanted via an anterior approach. The device is to be used in patients who have had at least six (6) weeks of non-operative treatment.

When used as a standalone system, Shoreline ACS is intended to be used as an adjunct to spinal fusion procedures at one level (C2-T1) and must be used with the Shoreline ACS bone screw fixation and locking cover.

When used with supplemental fixation, such as anterior cervical plates, the Shoreline Cervical low profile (TruProfile) Interbody Spacer is intended to be used as an adjunct to spinal fusion procedures at one or two 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K201646 - 510(k) Summary

Contact Details

Applicant Name: SeaSpine® Orthopedics Corporation

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

Primary Contact: Alicia McArthur, Regulatory Affairs Specialist
Secondary Contact: Jesse Albright, Regulatory Affairs Specialist

Date Prepared: August 7, 2020

Device Name

Trade Name: Shoreline ACS (Anterior Cervical 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			
K190655	OVE	Shoreline ACS (Anterior Cervical Standalone) System	SeaSpine Orthopedics Corporation
Additional Predicate Device			
K183083	OVE, ODP	Shoreline Cervical Interbody RT System	SeaSpine Orthopedics Corporation

Device Description

The Shoreline Anterior Cervical System (ACS) consists of the implant assembly composed of a single use PEEK cervical spacer (ASTM F2026) and a titanium alloy (ASTM F136) plate with titanium alloy variable angle or fixed bone screws, and a titanium alloy locking cover. Shoreline ACS is offered in a variety of footprints and heights to accommodate variations in patient anatomy and is generally box-shaped with surface teeth and a central canal for receiving autograft bone

graft material and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The system is implanted via an anterior approach.

The system offers spacers in low profile (TruProfile) and no profile versions. Both are available with a surface coating of commercially pure titanium (ASTM F67) referred to as NanoMetalene® (NM), bonded to PEEK. The spacers will be provided in gamma sterilized packaging; the bone screws, plate, and locking cover will be provided non-sterile for subsequent sterilization at the healthcare facility.

The instruments included with the Shoreline ACS System facilitate the placement, adjustment, and final locking of the interbody spacers, and removal if necessary. The instruments also include the trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

Indications for Use

The Shoreline ACS (Anterior Cervical System) are interbody fusion devices intended for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The Shoreline ACS implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous, cortical, and /or corticocancellous bone and implanted via an anterior approach. The device is to be used in patients who have had at least six (6) weeks of non-operative treatment.

When used as a standalone system, Shoreline ACS is intended to be used as an adjunct to spinal fusion procedures at one level (C2-T1) and must be used with the Shoreline ACS bone screw fixation and locking cover.

When used with supplemental fixation, such as anterior cervical plates, the Shoreline Cervical low profile (TruProfile) Interbody Spacer is intended to be used as an adjunct to spinal fusion procedures at one or two levels of the cervical spine (C2-T1).

Summary of Technological Characteristics

Shoreline ACS and predicate devices have the same operational principle; they act as a disc spacer and hold bone graft and include integrated fixation to maintain stability by direct purchase into the bony vertebral endplates. Shoreline ACS is substantially equivalent to the cited predicate device 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
- Anterior Plates

Non-Clinical Testing

The subject implants are the same as the predicate devices in terms of materials, sizes, and intended use. The subject device does not introduce a new worst-case. Engineering analyses of the modifications to Shoreline ACS determined that no additional mechanical testing was necessary.

Clinical Testing

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

Conclusions

The submitted data demonstrates that the subject Shoreline Anterior Cervical System (ACS) has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.