April 29, 2019

SeaSpine® Orthopedics Corporation
Alicia McArthur
Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K190655
Trade/Device Name: SeaSpine® Shoreline™ ACS- Anterior Cervical Standalone System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: March 28, 2019
Received: March 29, 2019

Dear Ms. McArthur:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K190655

Device Name
SeaSpine® Shoreline™ ACS- Anterior Cervical Standalone System

Indications for Use *(Describe)*
The SeaSpine® Shoreline™ ACS is a stand-alone device indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease of the cervical spine at a single level (C2-T1). The Shoreline™ ACS implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and implanted via an anterior approach. The cervical device is to be used in patients who have had at least six (6) weeks of non-operative treatment. The cervical device is to be used with bone screw fixation and a locking cover.

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.

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510(k) Summary

Contact Details

Applicant Name: SeaSpine® Orthopedics Corporation
Address: 5770 Armada Drive, Carlsbad CA

Phone number: (760) 216-5117
Fax number: (760) 683-6874

Contact person: Alicia McArthur, Specialist, Regulatory Affairs
Email address: alicia.mcarthur@seaspine.com

Date Prepared: March 13, 2019

Device Name

Trade Name: *SeaSpine® Shoreline™ ACS - Anterior Cervical Standalone System*

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral fusion device with integrated fixation, cervical (21 CFR 888.3080)

Class: II

Product Code: OVE

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K170569	OVE	*Shoreline™ ACS- Anterior Cervical Standalone System*	SeaSpine Orthopedics Corporation
ADDITIONAL PREDICATE			
K161081	OVE	*Shoreline™ ACS- Anterior Cervical Standalone System*	SeaSpine Orthopedics Corporation

Device Description

The *SeaSpine® Shoreline™ ACS - Anterior Cervical Standalone System* 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 and/or corticocancellous bone. The system is implanted via an anterior approach.

The system offers spacers in *Low-Profile* and *No-Profile* versions. Both *Low-Profile* and *No-Profile* spacers are available with a surface coating of commercially pure titanium (ASTM F67) referred to as NanoMetalene® (NM), bonded to PEEK. The *Low-Profile* version consists of a NanoMetalene bonded PEEK interbody and two-, three-, and four-hole titanium alloy plates. The *No-Profile* version consists of an interbody spacer with a two-hole anterior titanium alloy face section with a NanoMetalene bonded PEEK posterior section.

The *No-Profile* versions of the spacers are available in a standard lordotic angle, while the *Low-Profile Spacer* is offered in multiple lordotic versions. The *Shoreline™ ACS* spacers include radiographic markers manufactured from either titanium alloy (ASTM F136) or tantalum (ASTM F560).

No-Profile Implant versions are offered in a two-screw construct and the *Low-Profile* versions in two-, three-, and four-screw constructs to accommodate a range of surgeon preference. For all spacer, plate and screw variations, the locking cover attaches to the device and physically blocks the screw heads to prevent screw back out from the construct.

The *No-Profile* and *Low-Profile* NanoMetalene cervical 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.

Intended Use/Indications for use

The *SeaSpine® Shoreline™ ACS* is a stand-alone device indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease of the cervical spine at a single level (C2-T1). The *Shoreline™ ACS* implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and implanted via an anterior approach. The cervical device is to be used in patients who have had at least six (6) weeks of non-operative treatment. The cervical device is to be used with bone screw fixation and a locking cover.

Summary of Technological Characteristics

The *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. The *SeaSpine® Shoreline™ ACS* 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
- Anterior Plates

Non-Clinical Testing

Non-clinical mechanical testing was not performed on the subject devices. The subject implants are the same as the predicate devices in terms of materials, sizes, and intended use. The subject (modified) devices do not introduce a new worst-case. Engineering analyses of the modifications to the *SeaSpine® Shoreline™ ACS System* determined that no additional mechanical testing is necessary.

Clinical Testing

There was no clinical testing performed for this submission.

Conclusions

The submitted data demonstrate that the *SeaSpine® Shoreline™ ACS System* is substantially equivalent to the cited legally marketed predicates.