DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 14, 2016

SeaSpine Orthopedics Corporation
Ms. Jenny Fam
Sr. Director, Regulatory Affairs
5770 Armada Drive
Carlsbad, California 92008

Re: K161081
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: August 12, 2016
Received: August 15, 2016

Dear Ms. Fam:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161081

Device Name
SeaSpine Shoreline™ ACS - Anterior Cervical Standalone System

Indications for Use *(Describe)*
The Shoreline ACS device 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 nonoperative treatment. The cervical device is to be used with Shoreline bone screw fixation and the Shoreline 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.

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K161081
510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

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Phone number: (760) 216-5104
Fax number: (760) 683-6874

Contact person: Jenny Fam, Sr. Director, Regulatory Affairs
Email address: jenny.fam@seaspine.com

Date Prepared: September 6, 2016

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 per 21 CFR 888.3080

Product Code: OVE

Class: II

Legally Marketed Predicate and Reference Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PREDICATE Device			
K151939	OVE	Coalition	Globus Medical, Inc.
REFERENCE Devices			
K150053	OVE	Stalif c; Stalif c-ti	Centinel Spine,Inc.
K092521	OVE	Zuma-C	SeaSpine, Inc.
K142488	ODP	Cambria NanoMetalene	SeaSpine, Inc.

Device Description

The SeaSpine Shoreline™ ACS (Anterior Cervical Standalone) System consists of the implant assembly, associated instrumentation as well as caddies and trays that may be used for storage and organization. The implant assembly is composed of a 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. Low profile versions have minimal profile anterior to the disc space (1.6mm), while no profile versions have zero profile. Both low profile and no profile spacers are available with a surface coating of commercially pure titanium (ASTM F67) referred to as NanoMetalene® (NM). Alternatively, the no profile spacer is available

without a NanoMetalene® coating. Both low profile and no profile versions of the spacers are available in a standard lordotic angle. The Low Profile spacer will also be offered in multiple lordosis versions. The SeaSpine 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.

Intended Use/Indications for Use

The Shoreline ACS device 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 nonoperative treatment. The cervical device is to be used with Shoreline bone screw fixation and the Shoreline locking cover.

Comparison of Technological Characteristics

The SeaSpine Shoreline™ ACS is substantially equivalent to the cited predicate and reference devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

	Intended Use	Materials	Design	Mechanical Testing
Subject Device: SeaSpine Shoreline™ ACS	Single level cervical spinal fusion via anterior approach for skeletally mature patients with Degenerative Disc Disease (DDD)	Equivalent or similar materials: PEEK-OPTIMA per ASTM 2026), Titanium alloy (ASTM F136), Tantalum, (ASTM F560), CP Titanium Surface (ASTM F67)	Equivalent or similar spacer height, footprint, lordotic angle and screw/plate dimensions	Mechanical testing: Static/Dynamic torsion (ASTM F2077), Static/Dynamic axial compression (ASTM F2077), Static/Dynamic compression shear (ASTM F2077), Subsidence (ASTM F2267), Wear evaluation (ASTM F1877)
Predicate/Reference Devices: Globus Coalition SeaSpine Cambria NM SeaSpine Zuma-C Centinel Spine Stalif C/C-Ti	Single level cervical spinal fusion via anterior approach for skeletally mature patients with Degenerative Disc Disease (DDD)	Some or all of the following materials: PEEK-OPTIMA per ASTM 2026), Titanium alloy (ASTM F136), Tantalum, (ASTM F560), CP Titanium Surface (ASTM F67)	Various spacer height, footprint, lordotic angle and screw/plate dimensions	Some or all of the following testing: Static/Dynamic torsion (ASTM F2077), Static/Dynamic axial compression (ASTM F2077), Static/Dynamic compression shear (ASTM F2077), Subsidence (ASTM F2267), Wear evaluation (ASTM F1877), Expulsion

Non-clinical Testing

The SeaSpine Shoreline™ ACS demonstrated equivalent performance to the Globus predicate through static and dynamic compression, compression shear, and torsion testing per ASTM F2077, subsidence testing per ASTM F2267, and wear particle analysis per ASTM F1877.

Clinical Testing

No clinical testing was required to demonstrate equivalence.

Conclusions

The submitted data demonstrate that the SeaSpine Shoreline™ ACS is substantially equivalent to the cited legally marketed predicate devices; it is as safe, as effective, and performs at least as safely and effectively.