November 28, 2023

SeaSpine Orthopedics Corporation
Kendal Moulton
Regulatory Affairs Associate
5770 Armada Drive
Carlsbad, California 92008

Re: K233414
Trade/Device Name: Shoreline ACS Interbody System; Shoreline RT Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: October 6, 2023
Received: October 10, 2023

Dear Kendal Moulton:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233414

Device Name

Shoreline ACS Interbody System;
Shoreline RT Interbody System

Indications for Use *(Describe)*

Shoreline ACS Interbody System:

The Shoreline ACS Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. 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 Shoreline ACS Interbody System, which includes the TruProfile plates and No-profile spacer, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers. The Shoreline ACS interbody spacers with ≥ 20° lordosis are intended to be used with supplemental fixation.

When the Shoreline ACS Interbody (excluding the No-profile spacer) is used with supplemental fixation, such as anterior cervical plates, the Shoreline ACS Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

Shoreline RT Interbody System:

The Shoreline RT Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. 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 Shoreline RT Interbody System, which includes the TruProfile plates, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers. The Shoreline RT interbody spacers with ≥ 20° lordosis are intended to be used with supplemental fixation.

When the Shoreline RT Interbody System is used with supplemental fixation, such as anterior cervical plates, the Shoreline RT Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple 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

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Phone number: (760) 216-5176
Fax number: (760) 683-6874

Contact Person: Kendal Moulton, Regulatory Affairs Associate

Date Prepared: October 6, 2023

Device Name

Trade Name(s): Shoreline ACS Interbody System
Shoreline RT Interbody System

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Fusion Device with Bone Graft, Cervical (21 CFR 888.3080)
Intervertebral Fusion Device With Integrated Fixation, Cervical (21 CFR 888.3080)

Product Code(s): OVE, ODP

Device Class: 2

Legally Marketed Predicate Devices

510(k) Number	Product Code(s)	Trade Name(s)	Manufacturer
Primary Predicate Device			
K201193	OVE, ODP	Shoreline ACS (Anterior Cervical System) & Shoreline Cervical Interbody RT System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K212904	OVE, ODP	WaveForm C Interbody System	SeaSpine Orthopedics Corporation

Device Description

Shoreline ACS Interbody System

The Shoreline ACS Interbody System featuring NanoMetalene® surface technology consists of single-use anterior cervical intervertebral body fusion devices manufactured from

polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and/or titanium alloy (Ti-6Al-4V ELI per ASTM F136) markers for radiographic visualization and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67) that provides a microscopic roughened surface with nano-scale features. The interbody spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy. The spacers, which include a central graft window for receiving autogenous bone graft and/or allogenic bone graft material, are individually packaged in a double PETG/Tyvek tray configuration and gamma sterilized.

The Shoreline ACS Interbody System can be used with supplemental fixation, such as an anterior plate, or as a standalone construct in combination with non-sterile fixation implants (i.e., plates, bone screws, and locking covers) to create the TruProfile and No-profile configurations. Each TruProfile and No-profile construct must be used with the maximum number of screws allowed by the plate interface. The fixation implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136).

The system includes the associated non-sterile instruments that facilitate the placement, adjustment, and removal, if necessary, of the system implants as well as trays and caddies that may be used for storage, protection, and organization prior to and during the steam sterilization process for the non-sterile components.

Shoreline RT Interbody System

The Shoreline RT Interbody System featuring NanoMetalene® surface technology consists of single-use anterior cervical intervertebral body fusion devices manufactured from polyetheretherketone (PEEK) (per ASTM F2026) with tantalum (per ASTM F560) and/or titanium alloy (Ti-6Al-4V ELI per ASTM F136) markers for radiographic visualization and NanoMetalene, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67) that provides a microscopic roughened surface with nano-scale features. The interbody spacers are offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy. The spacers, which include a central graft window for receiving autogenous bone graft and/or allogenic bone graft material, are individually packaged in a double PETG/Tyvek tray configuration and gamma sterilized.

The Shoreline RT Interbody System can be used with supplemental fixation, such as an anterior plate, or as a standalone construct in combination with the Shoreline ACS Interbody System non-sterile fixation implants (i.e., plates, bone screws, and locking covers) to create the TruProfile configuration. Each TruProfile construct must be used with the maximum number of screws allowed by the plate interface. The fixation implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136).

The system includes the associated non-sterile instruments that facilitate the placement, adjustment, and removal, if necessary, of the system implants as well as trays and caddies that

may be used for storage, protection, and organization prior to and during the steam sterilization process for the non-sterile components.

Intended Use/Indications for Use

Shoreline ACS Interbody System

The Shoreline ACS Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. 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 Shoreline ACS Interbody System, which includes the TruProfile plates and No-profile spacer, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers. The Shoreline ACS interbody spacers with ≥ 20° lordosis are intended to be used with supplemental fixation.

When the Shoreline ACS Interbody (excluding the No-profile spacer) is used with supplemental fixation, such as anterior cervical plates, the Shoreline ACS Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

Shoreline RT Interbody System

The Shoreline RT Interbody System with NanoMetalene® surface technology are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for multiple contiguous levels. 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 Shoreline RT Interbody System, which includes the TruProfile plates, is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1) and must be used with bone screw fixation and locking covers. The Shoreline RT interbody spacers with ≥ 20° lordosis are intended to be used with supplemental fixation.

When the Shoreline RT Interbody System is used with supplemental fixation, such as anterior cervical plates, the Shoreline RT Interbody System is intended to be used as an adjunct to spinal fusion procedures at multiple contiguous levels of the cervical spine (C2-T1).

Summary of Technological Characteristics

The Shoreline ACS Interbody System and Shoreline RT Interbody System are identical or similar to the cited predicate systems in regard to intended use/indications for use, device description, technological characteristics (e.g., operating principle, design, components, materials, manufacturing, labeling, sterility, etc.), and non-clinical performance (i.e., mechanical testing).

Non-Clinical Testing

Mechanical performance in static and dynamic axial compression, compression shear, and torsion (per ASTM F2077) and subsidence (per ASTM F2267) was verified for the Shoreline ACS Interbody System and Shoreline RT Interbody System through engineering analysis.

Clinical Testing

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

Conclusions

The submitted data demonstrates that the Shoreline ACS Interbody System and Shoreline RT Interbody System are substantially equivalent to the cited legally marketed predicates.