SeaSpine Orthopedics Corporation
Kavita Chandrashekar
Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

August 30, 2021

Re: K211903
Trade/Device Name: Shoreline Threaded TruProfile® Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 18, 2021
Received: June 21, 2021

Dear Kavita Chandrashekar:

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,

for

Colin O'Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211903

Device Name
Shoreline Threaded TruProfile® Plate

Indications for Use *(Describe)*

The Shoreline Threaded TruProfile® Plate is intended for anterior cervical fixation (C2–T1) for the following indications:
• Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
• Spondylolisthesis,
• Trauma (i.e., fracture or dislocation),
• Spinal Stenosis,
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
• Tumor,
• Pseudarthrosis,
• Failed previous fusion.

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

K211903

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

Address: 5770 Armada Drive, Carlsbad CA
Phone number: (858) 405-1276 (Kavita)
Fax number: (760) 683-6874

Contact person: Kavita Chandrashekar, Regulatory Affairs Specialist, Regulatory Affairs

Date Prepared: June 18, 2021

Device Name

Trade Name: Shoreline Threaded TruProfile® Plate

Device Classification Regulation: 888.3060

Common Name: Cervical Plate

Classification Name: Spinal Intervertebral Body Fixation Orthosis

Class: II

Product Code: KWQ

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K202064	KWQ	SeaSpine Admiral Anterior Cervical Plate (ACP) System	SeaSpine Orthopedics Corporation
Additional Predicate Devices			
K190885	OVE, ODP, KWQ	Elevation Spine Saber-C System	Elevation Spine
K173521	KWQ	SeaSpine Cabo ACP System	SeaSpine Orthopedics Corporation

Device Description

The Shoreline Threaded TruProfile® Plate (referred to as the TruProfile Plate) is a spinal fixation system that consists of a variety of non-sterile, single-use plates, screws, and locking covers. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The Shoreline plates include locking covers that cover the heads of the bone screws to reduce the potential for screw back-out. The TruProfile Plate implant components are made from titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

The TruProfile Plate implant components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine (C2- T1) during the development of a cervical spinal fusion. Associated instruments are available to facilitate the implantation of the device. The instruments are placed in system-specific tray components for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/Indications for Use

The Shoreline Threaded TruProfile® Plate is intended for anterior cervical fixation (C2–T1) for the following indications:

- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Spinal Stenosis,
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- Tumor,
- Pseudarthrosis,
- Failed previous fusion.

Summary of Technological Characteristics

The TruProfile Plate is identical or similar to the cited predicate devices in regard to components, device description, intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

The plates are used to treat the same conditions, have essentially the same precautions and contraindications for use, and represent a basic design concept in terms of safety and effectiveness, and differ only in design details and not functionality.

Non-Clinical Testing

The TruProfile Plate has demonstrated equivalent mechanical performance to the predicate system through mechanical testing in static axial compression bending and torsion, and dynamic axial compression bending per ASTM F1717.

Conclusions

The submitted data demonstrates that the Shoreline TruProfile Plate is substantially equivalent to the cited legally marketed predicate.