February 3, 2023

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

Re: K220296
Trade/Device Name: Manta Ray TDF Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 23, 2023
Received: January 24, 2023

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 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220296

Device Name
Manta Ray TDF Spacer

Indications for Use *(Describe)*
The Manta Ray TDF Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-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.

The Manta Ray TDF Spacer is intended for use with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

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
Address: 5770 Armada Drive, Carlsbad, CA 92008
Phone number: (760) 216-5176
Fax number: (760) 683-6874
Contact Person: Jesse Albright, Associate Manager, Regulatory Affairs
Date Prepared: February 1, 2023

Device Name

Trade Name: Manta Ray TDF Spacer
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Fusion Device With Bone Graft, Cervical (21 CFR 888.3080)
Product Code(s): ODP
Device Class: 2

Legally Marketed Predicate Devices

510(k) Number	Product Code(s)	Trade Name	Manufacturer
Primary Predicate Device			
K183083	OVE, ODP	Shoreline Cervical Interbody RT System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K212904	OVE, ODP	SeaSpine WaveForm C Interbody System	SeaSpine Orthopedics Corporation
K101363	ODP	Vu cPOD Intervertebral Body Fusion Device	SeaSpine Orthopedics Corporation
K151496	ODP	Latitude-C Cervical Interbody Spacer System	DeGen Medical

Device Description

The Manta Ray TDF Spacer features a cervical interbody cage that engages the entire disc space, including the uncovertebral joints, during the fusion process. This engagement between the lateral wings and the uncovertebral joints is intended to further reduce subsidence by increasing the mating surface area. The interbody spacer is manufactured from polyetheretherketone (PEEK) (per ASTM F2026), tantalum (per ASTM F560) markers for radiographic visualization, and NanoMetalene®, which is a one-micron thick surface layer of commercially pure titanium (per ASTM F67). NanoMetalene surface technology provides a microscopic roughened surface with nano-scale features. Each spacer has a central graft window for receiving autograft and/or

allogenic bone graft material and is offered in a variety of footprints, heights, and lordotic options to accommodate variations in pathology and patient anatomy. The Manta Ray TDF Spacer is intended for use with supplemental fixation.

The instruments provided with the Manta Ray TDF Spacer facilitate the placement, adjustment, and removal, if necessary, of the interbody spacer. The spacer is provided sterile packaged, whereas the instruments are provided in system-specific trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/Indications for Use

The Manta Ray TDF Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-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.

The Manta Ray TDF Spacer is intended for use with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

Summary of Technological Characteristics

The Manta Ray TDF Spacer and the cited predicate devices have the same operational principle; they act as a disc spacer and hold bone graft. The subject device is also similar to the cited predicate devices in regard to intended use/indications for use, device description, technological characteristics (e.g., design, components, materials, manufacturing, labeling, sterility, etc.), and non-clinical performance (i.e., mechanical testing).

Compared to the predicate counterparts, the Manta Ray TDF Spacer is used to treat the same conditions, has essentially the same precautions and contraindications for use, and represents a basic design concept in terms of safety and effectiveness, differing only in design details and not functionality.

The subject and predicate devices are based on the following similar technological elements:

- Spacer Heights
- Spacer Footprints
- Spacer Lordotic Angles

Non-Clinical Testing

The Manta Ray TDF Spacer has demonstrated equivalent mechanical performance to the predicate devices through mechanical testing in static and dynamic compression per ASTM F2077, static and dynamic torsion per ASTM F2077, and subsidence per ASTM F2267.

Clinical Testing

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

Conclusions

The submitted data demonstrate that the Manta Ray TDF Spacer is substantially equivalent to the cited legally marketed predicates.