SeaSpine Orthopedics Corporation
Aly Alvarez
Sr. Specialist, Regulatory Affairs
5770 Armada Drive
Carlsbad, California 98008

April 24, 2020

Re: K193636
Trade/Device Name: SeaSpine Reef TH System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 23, 2020
Received: March 25, 2020

Dear Aly Alvarez:

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
Brent Showalter, Ph.D.
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193636

Device Name
SeaSpine Reef TH System

Indications for Use *(Describe)*

The Reef TH System is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous nonfusion spinal surgery at the involved spinal level(s). These patients should have had six months of nonoperative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous 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
Phone number: (760) 216-5622
Fax number: (760) 683-6874

Contact person: Aly Alvarez, Sr. Regulatory Affairs Specialist

Date Prepared: December 26, 2019

Device Name

Trade Name: SeaSpine Reef TH System

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral fusion device with bone graft, lumbar (21 CFR 888.3080)

Class: II

Product Code: MAX

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K082310	MAX	SeaSpine Spacer System – Pacifica	SeaSpine Orthopedics Corporation
Additional Predicate Devices			
K192132	MAX	SeaSpine Beachside System	SeaSpine Orthopedics Corporation

Device Description

The SeaSpine Reef TH System is an intervertebral fusion device with large central graft windows which are packed with autogenous bone graft and/or allogenic bone graft, composed of cancellous and/or corticocancellous bone prior to implantation. The implant is manufactured from PEEK (ASTM F2026) with tantalum (ASTM F560) and titanium alloy (ASTM F136) radiographic markers. The implants have a one-micron thick surface coat of commercially pure (CP) titanium (ASTM F67) and are sterile-packed. The instruments included with the system facilitate the placement and adjustment of the interbody spacer, and removal if necessary. The instruments are

placed in system-specific trays for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/Indications for Use

The Reef TH System is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous nonfusion spinal surgery at the involved spinal level(s). These patients should have had six months of nonoperative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and supplemental fixation.

Summary of Technological Characteristics

The SeaSpine Reef TH System 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, manufacturing, etc.) and performance (mechanical safety).

The implants 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

Mechanical performance in compression and compression-shear (ASTM F2077), subsidence (ASTM F2267), and wear testing (ASTM F1877) was performed for the Reef TH System. An engineering analysis of expulsion, packaging, shipping and sterilization tests was also conducted to validate a Sterility Assurance Level (SAL) of 10-6 and ensure maintenance of a sterile barrier. Bacterial Endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

No additional coating characterization testing was conducted in this submission due to coating being identical to the predicate.

Clinical Testing

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

Conclusions

The submitted data demonstrates that the SeaSpine Reef TH System is as safe, as effective, and performs at least as safely and effectively as the cited legally marketed predicate.