SeaSpine Orthopedics Corporation
Ms. Gina Flores
Specialist Regulatory Affairs
5770 Armada Drive
Carlsbad, California 92008

July 18, 2018

Re: K181079
Trade/Device Name: SeaSpine Regatta Lateral System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: April 24, 2018
Received: April 25, 2018

Dear Ms. Flores:

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 Part 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181079

Device Name
SeaSpine Regatta Lateral System

Indications for Use *(Describe)*

The SeaSpine Regatta Lateral System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

The SeaSpine Regatta Lateral System is intended for use with 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

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Phone number: (760) 216-5136
Fax number: (760) 683-6874

Contact person: Gina Flores, Sr. Regulatory Specialist
Email address: gina.flores@seaspine.com

Date Prepared: April 23, 2018

Device Name

Trade Name: SeaSpine Regatta Lateral System

Common Name: Intervertebral Fusion Device with Bone Graft, Lumbar

Classification Name: Intervertebral body fusion device (21 CFR 888.3080)

Product Code: MAX

Class: II

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K112986	MAX, OVD	Vu a•POD-L Intervertebral Fusion Device	SeaSpine Orthopedics Corporation (formerly Integra LifeSciences, Inc.)
Additional PREDICATE Device			
K142488	MAX	Vu a•POD-L Intervertebral Fusion Device	SeaSpine Orthopedics Corporation
K162351	OVD	Vu a•POD Prime NanoMetalene	SeaSpine Orthopedics Corporation

Device Description

The SeaSpine Regatta Lateral System is an intervertebral body fusion device (IBD) with large central graft windows, which are packed with autogenous bone graft and/or allogeneic bone graft, composed of cancellous and/or corticocancellous bone prior to implantation. The spacer has a bulleted insertion end for ease of implantation and tantalum markers to allow easier radiological assessment of the spacer position and orientation. The spacers are manufactured from PEEK (ASTM F2026) with radiographic markers manufactured from tantalum (ASTM F560), with a one-micron thick surface of commercially pure (CP) titanium (ASTM F67), and sterile packaged. The instruments included with the system facilitate the placement and adjustment of the interbody spacer, and removal if necessary. The instruments are placed in trays for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/Indications for use

The SeaSpine Regatta Lateral System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

The SeaSpine Regatta Lateral System is intended for use with supplemental fixation.

Summary of Technological Characteristics

The SeaSpine Regatta Lateral System and the predicate device have the same operational principle; they act as a disc spacer and hold bone graft to promote fusion in the lumbar spine. The SeaSpine Regatta Lateral System is similar to the cited predicate devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

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

- Same widths and heights
- Similar lordotic angles
- Implant Materials: PEEK, Tantalum, CP Titanium
- Markers for radiographic visualization
- Instrumentation

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 expulsion testing was verified for the Regatta Lateral System through engineering analysis.

Packaging, shipping and sterilization tests were performed 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.

Clinical Testing

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

Conclusions

The submitted data demonstrate that the SeaSpine Regatta Lateral System is as safe, as effective, and performs at least as safely and effectively as the cited legally marketed predicate device.