May 23, 2019

SeaSpine Orthopedics Corporation
Martin Yahiro, M.D.
Director, Medical Affairs
5770 Armada Drive
Carlsbad, California 92008

Re: K183639
Trade/Device Name: Mariner Outrigger Revision System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: December 20, 2018
Received: December 26, 2018

Dear Dr. Yahiro:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

for CAPT Raquel Peat, PhD, MPH, USPHS
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)*
K183639

Device Name
Mariner Outrigger Revision System

Indications for Use *(Describe)*

When used with the Mariner, Daytona Small Stature, Malibu, Newport, and Coral Spinal Systems:
The Mariner Outrigger Revision System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/ilium) in the treatment of the following acute and chronic instabilities or deformities:
• degenerative disc disease (defined as discogenic back pain 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 (i.e., failed previous fusion)

When used with Daytona Small Stature Spinal System for posterior non-cervical pedicle screw fixation in pediatric patients, the Mariner Outrigger Revision System is also indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis (AIS), neuromuscular scoliosis, and congenital scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

The Mariner Outrigger Revision System is intended to be used with autograft or allograft.

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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(760) 683-6874

Contact person: Martin Yahiro, M.D., Director, Medical Affairs
Email address: martin.yahiro@seaspine.com

Date Prepared: April 23, 2019

Device Name

Trade Name: Mariner Outrigger Revision System

Common Name: Pedicle Screw Spinal System

Classification Name: 21 CFR 888.3070- Thoracolumbosacral Pedicle Screw
21 CFR 888.3050- Spinal Interlaminal Fixation Orthosis
21 CFR 888.3060- Spinal Intervertebral Body Fixation Orthosis

Class: II

Product Code: NKB

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K173882	NKB	Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation
ADDITIONAL PREDICATE Device			
K163604, K180686	NKB, OSH, KWP, KWQ	Daytona Small Stature System	SeaSpine Orthopedics Corporation
K170647, K172194	NKG, KWP, NKB, KWQ	Connector System	Orthofix Inc.

Device Description

The Mariner Outrigger Revision System is a thoracolumbar revision system designed to help reduce the trauma associated with revision surgeries by allowing the user the option to leave the existing hardware in and extend the construct or remove and replace with new SeaSpine hardware.

The Mariner Outrigger Revision System includes a variety of non-sterile implants manufactured from titanium alloy or cobalt chrome alloy and is comprised of various axial and parallel connectors of different shapes, rod slots, and also of various rods. The Mariner Outrigger Revision System is compatible with other SeaSpine posterior spinal fixation systems (e.g. Mariner, Daytona Small Stature, Malibu, Newport, and Coral Spinal Systems) which offer titanium and/or cobalt chrome alloy rods ranging in sizes of Ø4.5mm to Ø6.35mm.

The Mariner Outrigger Revision implants are manufactured from titanium alloy Ti-6Al-4V ELI (per ASTM F136), or cobalt chrome alloy (per ASTM F562). The instruments included in the system facilitate the placement, removal, adjustment, and final locking of the system implants. Other accessories to the system also include the trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/Indications for use

When used with the Mariner, Daytona Small Stature, Malibu, Newport, and Coral Spinal Systems:

The Mariner Outrigger Revision System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/ilium) in the treatment of the following acute and chronic instabilities or deformities:

- degenerative disc disease (defined as discogenic back pain 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),
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When used with Daytona Small Stature Spinal System for posterior non-cervical pedicle screw fixation in pediatric patients, the Mariner Outrigger Revision System is also indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis (AIS), neuromuscular scoliosis, and congenital scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

The Mariner Outrigger Revision System is intended to be used with autograft or allograft.

Summary of Technological Characteristics

The Mariner Outrigger Revision System is 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).

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

- Utilize similar rods
- Utilize similar connectors
- Have similar locking caps
- Same implant materials; titanium alloy (ASTM F136) and cobalt chrome alloy (ASTM F562)

Non-Clinical Testing

The Mariner Outrigger Revision System demonstrated similar performance to the predicate systems through static and dynamic mechanical testing with reference to ASTM F1717 and ASTM F1798.

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 Mariner Outrigger Revision System is substantially equivalent to the cited legally marketed predicate.