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

Re: K173882
Trade/Device Name: SeaSpine Mariner Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw Systems
Regulatory Class: Class II
Product Code: NKB
Dated: February 2, 2018
Received: February 5, 2018

Dear Gina 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Colin O'neill -S for MNM

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173882

Device Name
SeaSpine Mariner Pedicle Screw System

Indications for Use *(Describe)*

The intended use of the Mariner Pedicle Screw System is to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The indications for use are as follows:
- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion,
- spondylolisthesis,
- trauma (i.e., fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- spinal tumor,
- pseudoarthrosis, and/or
- 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

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: December 20, 2017

Device Name

Trade Name: SeaSpine Mariner Pedicle Screw System

Common Name: Pedicle Screw Spinal System

Classification: 21 CFR 888.3070

Classification Name: Thoracolumbosacral Pedicle Screw

Class: II

Product Code: NKB

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K160902	NKB	SeaSpine Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation
ADDITIONAL PREDICATE Devices			
K122571, K072605, K061342, K051942, K051663	NKB	SeaSpine Malibu Spinal System	SeaSpine Orthopedics Corporation

Device Description

The Mariner Pedicle Screw System is a non-cervical spinal fixation device and instrumentation system intended for use as a posterior pedicle screw fixation system, a posterior non-pedicle screw fixation system, or as an anterolateral fixation system. The system consists of single-use implants including fixed, polyaxial, cephalad/caudal restricted-motion, and medial/lateral restricted motion pedicle screws as well as connecting spinal rods and a separate locking element.

The Mariner implants are manufactured from titanium alloy Ti-6Al-4V ELI (per ASTM F136), and cobalt chrome (Co-35Ni-20Cr-10Mo per ASTM F562 and Co-28Cr-6Mo-alloy 1 (warm worked) per ASTM F1537). The instruments included in the Mariner Pedicle Screw 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

The intended use of the Mariner Pedicle Screw System is to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The indications for use are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- spinal tumor
- pseudarthrosis, and/or
- failed previous fusion.

Summary of Technological Characteristics

The SeaSpine Mariner Pedicle Screw 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).

All 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.

Non-Clinical Testing

The SeaSpine Mariner Pedicle Screw 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 SeaSpine Mariner Pedicle Screw System is substantially equivalent to the cited legally marketed predicate.