July 19, 2019

SeaSpine Orthopedics Corporation
Ms. Aly Alvarez
Senior Regulatory Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K191648
Trade/Device Name: Mariner MIS Pedicle Screw System; SeaSpine Navigation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWQ, OLO
Dated: June 19, 2019
Received: June 21, 2019

Dear Ms. 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,

Ronald P. Jean, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191648

Device Name
Mariner MIS Pedicle Screw System

Indications for Use *(Describe)*
The intended use of the Mariner Pedicle Screw System in a posterior or anterolateral approach 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
-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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K191648

Device Name
SeaSpine Navigation System

Indications for Use *(Describe)*
The SeaSpine Navigation System reusable instruments are intended to be used during the preparation and placement of SeaSpine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The SeaSpine Navigation reusable instruments are specifically designed for use with the Medtronic Stealth Station System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

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)

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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

Primary contact: Alicia McArthur, Regulatory Specialist
Email address: alicia.mcarthur@seaspine.com
Secondary contact: Aly Alvarez, Sr. Regulatory Specialist
Email address: alyssa.alvarez@seaspine.com

Date Prepared: June 18, 2019

Device Name

Trade Name:
1. Mariner MIS Pedicle Screw System
2. SeaSpine Navigation System

Common Name:
1. Pedicle Screw Spinal System; Spinal Intervertebral Body Fixation Appliance
2. Orthopedic Stereotaxic instrument

Classification:
1. 21 CFR 888.3070; 21 CFR 888.3060
2. 21 CFR 882.4560

Classification Name:
1. Thoracolumbosacral Pedicle Screw System, Spinal Intervertebral Body Fixation Orthosis
2. Stereotaxic Instrument

Class:
1. II
2. II

Product Code:
1. NKB, KWQ
2. OLO

Legally Marketed Predicate Devices

1.

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K160902	NKB	Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation

2.

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K172517	OLO	SeaSpine Navigation 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 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.

The *SeaSpine Navigation System* instruments are manual, surgical instruments that assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. The SeaSpine Navigation Instruments will be incorporated into the *Mariner Pedicle Screw System.*

With an increased demand for less invasive posterior fixation, the *Mariner MIS Pedicle Screw System* will offer instrumentation to its existing modular implant design to assist surgeons with MIS techniques.

Intended Use/Indications for use

1. The intended use of the *Mariner Pedicle Screw System* in a posterior or anterolateral approach 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
- 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.

2. The SeaSpine® Navigation System reusable instruments are intended to be used during the preparation and placement of SeaSpine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The SeaSpine® Navigation System reusable instruments are specifically designed for use with the Medtronic® StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

Summary of Technological Characteristics

The *Mariner MIS 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 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.

The *SeaSpine Navigation System* is similar to the cited predicated devices in regard to components, indications for use, technology, and performance specifications.

Non-Clinical Testing

Non-clinical mechanical testing was not performed on the subject devices. The subject devices are the same as the predicate devices in terms of materials, sizes, and intended use. The subject devices do not introduce a new worst case. Engineering analyses of the subject devices determined that no additional mechanical testing is necessary.

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 MIS Pedicle Screw System* and the *SeaSpine Navigation System* is substantially equivalent to the cited legally marketed predicates.