June 23, 2021

SeaSpine Orthopedics Corporation
Jesse Albright
Senior Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K211606
Trade/Device Name: Mariner Deformity System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: May 21, 2021
Received: May 25, 2021

Dear Jesse Albright:

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,

Colin O'Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211606

Device Name
Mariner Deformity 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.

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510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

Address: 5770 Armada Drive, Carlsbad, CA 92008
Phone number: (760) 216-5176
Fax number: (760) 683-6874

Contact Person: Jesse Albright, Senior Regulatory Affairs Specialist

Date Prepared: May 21, 2021

Device Name

Trade Name: Mariner Deformity System

Common Name: Thoracolumbosacral Pedicle Screw System
Spinal Intervertebral Body Fixation System
Spinal Interlaminal Fixation System

Classification Name: Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070)
Appliance, Fixation, Spinal Intervertebral Body (21 CFR 888.3060)
Appliance, Fixation, Spinal Interlaminal (21 CFR 888.3050)

Product Code(s): NKB, KWQ, KWP

Device Class: 2

Legally Marketed Predicate Devices

510(k) Number	Product Code(s)	Trade Name	Manufacturer
Primary Predicate Device			
K160902	NKB, KWQ, MNH, MNI	Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K191648	NKB, KWQ	Mariner MIS Pedicle Screw System	SeaSpine Orthopedics Corporation
K122571	NKB, KWP, MNI, MNH	Malibu Spinal System with the Daytona Deformity 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 fixation system, and/or 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, crossbars, connectors, and a separate locking element. The Mariner implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and/or cobalt chrome alloys (Co-28Cr-6Mo per ASTM F1537 or Co-35Ni-20Cr-10Mo per ASTM F562). 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 include trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

The Mariner Deformity System provides additional implants and instruments that expand the functionality of the Mariner platform and provide surgeons with a comprehensive modular system to address adult deformity applications. Additional implants include pre-contoured and constrained rods, uni-planar and fenestrated screws, hooks, lateral connectors, and modular screw heads, including those with a rigidly attached rod connector, as well as instruments for pedicle subtraction osteotomy, iliac fixation, reduction, derotation, and correction.

Intended Use/Indications for Use

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.

Summary of Technological Characteristics

The Mariner Deformity System is identical or similar to the cited predicate systems in regard to intended use/indications for use, device description, technological characteristics (e.g., operating

principle, design, components, materials, manufacturing, labeling, sterility, etc.), and non-clinical performance (i.e., mechanical testing).

Non-Clinical Testing

The Mariner Deformity System demonstrated equivalent mechanical performance to the predicate systems through static and dynamic mechanical testing with reference to ASTM F1717.

Clinical Testing

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

Conclusions

The submitted data demonstrate that the Mariner Deformity System is substantially equivalent to the cited legally marketed predicates.