DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2016

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

Re: K160902
Trade/Device Name: Mariner Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWQ
Dated: May 20, 2016
Received: May 23, 2016

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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)*
K160902

Device Name
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, Regulatory Affairs Specialist
Email address: gina.flores@seaspine.com

Date Prepared: May 20, 2016

Device Name

Trade Name: Mariner Pedicle Screw System

Common Name: Pedicle Screw Spinal System

Classification Name: Pedicle Screw Spinal System (21 CFR 888.3070)
Orthosis, Spondylolisthesis Spinal Fixation (21 CFR 888.3070)
Orthosis, Spinal Pedicle Fixation (21 CFR 888.3070)
Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)

Class: III, II

Product Code: NKB, MNH, MNI, KWQ

Legally Marketed Predicate and Reference Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K053276	NKB MNH MNI	IST Pedicle Screw System	SeaSpine, Inc. (originally Innovative Spinal Techniques (IST), then Integra Spine)
Additional Predicate Devices			
K051663 K051942 K061342 K072605	NKB MNH MNI	Malibu Spinal System	SeaSpine, Inc.
K043232 K021623	MNH MNI KWP	UCR Spinal System	SeaSpine, Inc.
K083089	NKB MNH MNI	Newport Spinal System	SeaSpine, Inc.

Device Description

The SeaSpine Mariner Pedicle Screw system is a system consisting of instruments and single-use implants intended to build constructs within the body to act as a temporary or permanent posterior, non-cervical pedicle fixation system, or an anterolateral fixation system to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusions to occur.

The Mariner implants are manufactured solely from titanium alloy (Ti-6Al-4V ELI per ASTM F136). The instruments included in the Mariner System facilitate the placement, removal, adjustment, and final locking of the system implants. The instruments 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,
- pseudoarthrosis, and/or
- failed previous fusion.

Substantial Equivalence Comparison

The SeaSpine Mariner System is similar to the cited predicate device in regards 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 System demonstrated similar performance to the predicate and reference systems through static and dynamic cantilever mechanical testing with reference to ASTM F1717 and screw head disassociation testing.

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 System is substantially equivalent to the cited legally marketed predicate.