February 20, 2018

SeaSpine Orthopedics Corporation
Ms. Gina Flores
Senior Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 90228

Re: K180176
Trade/Device Name: SeaSpine NewPort Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: January 26, 2018
Received: January 29, 2018

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 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,

Ronald P. Jean -S for

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)*

K180176

Device Name
SeaSpine NewPort Spinal System

Indications for Use *(Describe)*

The SeaSpine NewPort Spinal System is intended for posterior, non-cervical pedicle fixation to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine for the following indications:

- 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 Affairs Specialist
Email address: gina.flores@seaspine.com

Date Prepared: January 17, 2018

Device Name

Trade Name: SeaSpine NewPort Spinal System

Common Name: Pedicle Screw System

Classification Name: Thoracolumbosacral Pedicle Screw System

Class: II

Product Code: NKB

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K161535	NKB	SeaSpine NewPort Spinal System	SeaSpine Orthopedics Corporation
Additional Predicate Devices			
K083089	NKB	SeaSpine NewPort Spinal System	SeaSpine Orthopedics Corporation
K122571, K072605, K061342, K051942, K051663	NKB	SeaSpine Malibu System	SeaSpine Orthopedics Corporation

Device Description

The SeaSpine NewPort Spinal System consists of pedicle screws, locking caps and rods, and is intended to act as a temporary or permanent posterior, non-cervical pedicle fixation implant to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusions to occur.

The NewPort implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) with a cobalt washer (Co-28Cr/6Mo per ASTM F1537). The NewPort screws are offered in a variety of lengths and diameters and NewPort rods are offered in a variety of lengths to accommodate patient anatomy. The instruments included in the NewPort System facilitate the placement, removal, adjustment, and final locking of the system implants. The instruments also include the trays and caddies for protection during storage and the steam sterilization process. The trays and caddies also provide a means for organization of the instruments during the surgical procedure.

Intended Use/Indications for Use

The SeaSpine NewPort Spinal System is intended for posterior, non-cervical pedicle fixation to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine for the following indications:

- 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.

Summary of Technological Characteristics

The NewPort Spinal System and predicate devices have the same operational principle; the devices are designed to operate as a spinal fixation device designed to aid in the surgical correction and stabilization of the spine during the development of a solid fusion. The SeaSpine NewPort Spinal System is substantially equivalent to the cited predicate devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

The subject and predicate device are based on the following similar technological elements:

- Screw lengths
- Screw diameters
- Same implant materials, titanium alloy (Ti-6Al-4V ELI per ASTM F136) and cobalt chrome (Co-28Cr/6Mo per ASTM F1537)
- Utilize the same NewPort housing (extended tab), pin, and locking cap, and are used with the NewPort MIS and cap/rod combination rods.

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 minor design details and not functionality.

Non-Clinical Testing

SeaSpine conducted mechanical testing to demonstrate substantial equivalence between the NewPort Spinal System (subject) and the predicate systems. The subject NewPort Spinal System demonstrated substantial equivalent performance to the predicate systems through static and dynamic mechanical testing in accordance with ASTM F1717-15.

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 NewPort Spinal System is substantially equivalent to the cited legally marketed predicate.