DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

September 8, 2016

Re: K161535
Trade/Device Name: SeaSpine® NewPort™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: June 16, 2016
Received: June 17, 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" (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.

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,

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)*

K161535

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

1. Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

Address: 5770 Armada Drive, Carlsbad, CA 92008

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: August 30, 2016

2. Device Name

Trade Name: SeaSpine® NewPort™ Spinal System

Common Name: Pedicle Screw Spinal System

Classification Name: Pedicle Screw Spinal System (21 CFR 888.3070)
Product Code: NKB, Class III
Product Code: MNH, Class II
Product Code: MNI, Class II

3. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K083089 (Primary Predicate)	NKB, MNH, MNI	NewPort™ System	SeaSpine, Inc.
K053276 (Additional Predicate)	NKB, MNH, MNI	IST Pedicle Screw System	SeaSpine, Inc.
K051663 K051942 K061342 K072605 (Additional Predicate)	NKB, MNH, MNI	Malibu™ Spinal System	SeaSpine, Inc.

4. Device Description

The purpose of this submission is to add additional screw sizes, rods, locking cap and combination spinal cap and rod devices (cap/rod combos) for additional construct options.

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 system also includes instruments to assist with implantation, and a tray for organization and storage.

5. 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.

6. Substantial Equivalence Comparison

The SeaSpine® NewPort™ Spinal System is substantially equivalent to the cited

predicate devices with respect to intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

7. Non-clinical Testing

The SeaSpine® NewPort™ Spinal System demonstrated equivalent performance to the predicate systems when the following mechanical tests were performed:

- Dynamic Axial Compression
- Static Axial Compression
- Static Axial Torsion per ASTM F1717

8. Clinical Testing

No clinical testing was required to demonstrate equivalence.

9. Conclusions

The submitted data demonstrate that the SeaSpine® NewPort™ Spinal System is as safe, as effective, and performs at least as safely and effectively as the cited legally marketed predicate devices.