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

March 9, 2017

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

Re: K163604
Trade/Device Name: SeaSpine® Daytona® Small Stature Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: December 20, 2016
Received: December 21, 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 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.

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)*
K163604

Device Name
SeaSpine® Daytona® Small Stature Spinal System

Indications for Use *(Describe)*
The SeaSpine Daytona Small Stature 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. 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 fusion 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.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Daytona Small Stature Spinal System is indicated as an adjunct to fusion in the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including adolescent idiopathic scoliosis (AIS), neuromuscular scoliosis, and congenital scoliosis. Additionally, the Daytona Small Stature Spinal System is intended to treat pediatric patients diagnosed with spondylolisthesis/ spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. The devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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 Specialist
Email address: gina.flores@seaspine.com

Date Prepared: February 16, 2017

Device Name

Trade Name: SeaSpine® Daytona® Small Stature Spinal System

Common Name: Pedicle Screw Spinal System

Classification: 21 CFR 888.3070

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 MNH MNI	Newport® Spinal System	SeaSpine® Orthopedics Corporation
ADDITIONAL PREDICATE Devices			
K122571 K072605 K061342 K051942 K051663	NKB MNH MNI	Malibu® Spinal System	SeaSpine® Orthopedics Corporation
K152632	NKB OSH MNH MNI KWP KWQ	XIA® 4.5 Spinal System	Stryker® Corporation

Device Description

The Daytona® Small Stature Spinal 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 polyaxial and monoaxial pedicle screws as well as connecting spinal rods and a separate locking element. All implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and Cobalt Chrome alloy (Co-28Chromium-6Molybdenum per ASTM F1537).

Intended Use/Indications for use

The SeaSpine Daytona Small Stature 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. 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 fusion 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.

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Summary of Technological Characteristics

The SeaSpine® Daytona® Small Stature Spinal System is similar to the cited predicate devices 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® Daytona® Small Stature Spinal System demonstrated similar performance to the predicate systems through static compression bending, dynamic compression fatigue, and static torsion mechanical testing per ASTM F1717.

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® Daytona® Small Stature Spinal System is substantially equivalent to the cited legally marketed predicate.