May 14, 2018

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

Re: K180686
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, OSH, KWP, KWQ
Dated: March 14, 2018
Received: March 15, 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,

Colin O'neill -S for MNM

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180686

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 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; 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.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the SeaSpine Daytona Small Stature Spinal System may be used for the above indications as an adjunct to fusion in skeletally mature patients.

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.

The Daytona Small Stature Spinal System can be attached to SeaSpine's Atoll OCT Spinal System, Sierra Spinal System, or Malibu Spinal System using the rod connectors. Refer to the Atoll, Sierra, or Malibu System's Package Insert for the indications for use for those systems.

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
Phone number: (760) 216-5136
Fax number: (760) 683-6874

Contact person: Gina Flores, Regulatory Specialist
Email address: gina.flores@seaspine.com

Date Prepared: May 10, 2018

Device Name

Trade Name: SeaSpine Daytona Small Stature Spinal System

Common Name: Pedicle Screw Spinal System

Classification Name: 21 CFR 888.3070- Thoracolumbosacral pedicle screw system
21 CFR 888.3050- Spinal interlaminal fixation orthosis
21 CFR 888.3060- Spinal intervertebral body fixation orthosis.

Class: II

Product Code: NKB, OSH, KWP, KWQ

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K163206	NKB, OSH	SeaSpine Daytona Small Stature Spinal System	SeaSpine Orthopedics Corporation
ADDITIONAL PREDICATE Devices			
K122571, K072605, K061342, K051942, K051663	NKB	SeaSpine Malibu Spinal System	SeaSpine Orthopedics Corporation
K140276	NKB, OSH	CD Horizon Spinal System	Medtronic Sofamor Danek

Device Description

The SeaSpine 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 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-28Cr-6Mo per ASTM F1537).

Intended Use/Indications for use

The SeaSpine Daytona Small Stature Spinal System is intended for posterior, non-cervical 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; 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.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the SeaSpine Daytona Small Stature Spinal System may be used for the above indications as an adjunct to fusion in skeletally mature patients.

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.

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Summary of Technological Characteristics

The SeaSpine Daytona Small Stature Spinal System and predicate devices have the same operational principle; they are spinal fixation devices designed to aid in the surgical correction and stabilization of the spine during the development of a solid fusion.

The SeaSpine Daytona Small Stature Spinal System is identical or similar to the cited predicate devices in regard to components, device description, intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical).

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

- Utilize similar polyaxial and monoaxial cannulated screws
- Utilize the similar straight and precontoured rods
- Utilize similar hooks (laminar, pedicle, angled, and offset)
- Have similar locking caps
- Same implant materials; Titanium alloy (Ti-6AL-4V ELI per ASTM F136) and Cobalt Chrome alloy (Co-28Cr-6Mo per ASTM F1537)

Non-Clinical Testing

The SeaSpine Daytona Small Stature Spinal System demonstrated similar performance to the predicate systems through the following mechanical testing:

- Dynamic Compression Bending, Static Torsion, and Static Compression Bend per ASTM F1717, and
- Axial Slip, Static A-P, and Static Flexion-Extension per ASTM F1798

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 predicates.