February 28, 2020

SeaSpine® Orthopedics Corporation
Ms. Alicia McArthur
Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K200381
Trade/Device Name: Daytona® Small Stature Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: February 12, 2020
Received: February 18, 2020

Dear Ms. McArthur:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K200381

Device Name
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; 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 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 also 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 other cleared SeaSpine posterior fixation systems (e.g. Atoll OCT, Sierra Malibu, Daytona and Mariner Spinal Systems) using the rod connectors. Refer to the package inserts 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.**

# 510(k) Summary

## Contact Details

Applicant Name: SeaSpine® Orthopedics Corporation

Address: 5770 Armada Drive, Carlsbad CA
Phone number: (760) 216-5117
Fax number: (760) 683-6874

Primary Contact: Alicia McArthur, Regulatory Affairs Specialist

Date Prepared: February 12, 2020

## Device Name

Trade Name: Daytona® Small Stature Spinal System

Common Name: Pedicle Screw Spinal System

Classification Name: Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070)
Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050)
Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)

Class: II

Product Code: NKB, KWP, KWQ

## Legally Marketed Predicate Devices

| 510(k) Number | Product Code | Trade Name | Manufacturer |
|---|---|---|---|
| **Primary Predicate Device** | | | |
| K180686 | NKB, OSH, KWP, KWQ | Daytona® Small Stature Spinal System | SeaSpine® Orthopedics Corporation |
| **Additional Predicate Device(s)** | | | |
| K163604 | NKB, | Daytona® Small Stature Spinal System | SeaSpine® Orthopedics 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, as a posterior non-pedicle screw fixation system, or as an anterolateral fixation system. The system consists of

single-use implants, including monoaxial, polyaxial, and uniplanar screws, rods, locking caps, crossbars, hooks, and connectors. 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 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; 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 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 also 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 other cleared SeaSpine posterior fixation systems (e.g. Atoll OCT, Sierra Malibu, Daytona and Mariner Spinal Systems) using the rod connectors. Refer to the package inserts for the indications for use for those systems.

**Summary of Technological Characteristics**

The Daytona® Small Stature Spinal System is identical or similar to the cited predicate device in regard to intended use/indications for use, device description, technological characteristics (i.e., operating principle, design, components, materials, manufacturing, labeling, etc.), and non-clinical performance (i.e., mechanical testing).

All implants are used to treat the same conditions, have essentially the same precautions and contraindications for use, represent a basic design concept in terms of safety and effectiveness, and differ only in design details and not functionality.

**Non-Clinical Testing**

The Daytona® Small Stature Spinal System demonstrated similar mechanical performance to the predicate system based on mechanical testing per ASTM F1798.

## Clinical Testing

Not applicable. The determination of substantial equivalence is not based on an assessment of clinical performance data.

## Conclusions

The submitted data demonstrates that the Daytona® Small Stature Spinal System is substantially equivalent to the cited legally marketed predicate device for its intended use.