July 29, 2022

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

Re: K193224
Trade/Device Name: Daytona® Small Stature Growth Rod Conversion Set
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM

Dear Alicia McArthur:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 13, 2020. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

February 13, 2020

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

Re: K193224
Trade/Device Name: Daytona® Small Stature Growth Rod Conversion Set
Regulatory Class: Unclassified
Product Code: PGM
Dated: January 31, 2020
Received: February 4, 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,

Colin O'neill -S for

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)*
K193224

Device Name
Daytona® Small Stature Growth Rod Conversion Set

Indications for Use *(Describe)*
The Daytona® Small Stature Growth Rod Conversion Set is indicated in patients under 10 years of age with potential for additional spinal growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The extended axial connectors may be used with any cleared Daytona® Small Stature Spinal System rod construct. The Daytona® Small Stature Growth Rod Conversion Set is not intended to be used in conjunction with staples.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: Jesse Albright, Regulatory Affairs Specialist
Secondary Contact: Alicia McArthur, Regulatory Affairs Specialist

Date Prepared: January 31, 2020

Device Name

Trade Name: Daytona® Small Stature Growth Rod Conversion Set

Common Name: Growing Rod System

Classification Name: Growing Rod System (Unclassified)

Class: Unclassified

Product Code: PGM

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K142114	PGM	Xia® Growth Rod Conversion Set	Stryker Corporation

Device Description

The Daytona® Small Stature Growth Rod Conversion Set is a non-cervical spinal device intended to convert a traditional fusion construct into a non-fusion, growth- enabling construct that can be surgically lengthened on a periodic basis as the patient grows. The system consists of single-use extended axial connectors designed to interact with constructs consisting of hooks, screws, connectors, and rods. All implants are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

Intended Use/Indications for Use

The Daytona® Small Stature Growth Rod Conversion Set is indicated in patients under 10 years of age with potential for additional spinal growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The extended axial connectors may be used with any cleared Daytona® Small Stature Spinal System rod construct. The Daytona® Small Stature Growth Rod Conversion Set is not intended to be used in conjunction with staples.

Summary of Technological Characteristics

The Daytona® Small Stature Growth Rod Conversion Set 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 Growth Rod Conversion Set 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 Growth Rod Conversion Set is substantially equivalent to the cited legally marketed predicate device for its intended use.