March 25, 2020

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

Re: K193615
Trade/Device Name: NorthStar™ OCT Spinal System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: December 23, 2019
Received: December 26, 2019

Dear Alicia 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, M.B.E.
Acting Assistant Director
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)*

K193615

Device Name
NorthStar™ OCT Spinal System

Indications for Use *(Describe)*

The NorthStar OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, cervical spine (C1-C7) and upper thoracic spine (T1-T3):

- Traumatic spinal fractures and/or traumatic dislocations;
- Instability or deformity;
- Failed previous fusion (e.g. pseudoarthrosis);
- Tumors involving the cervical/thoracic spine;
- Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and
- Degenerative disease of the facets with instability.

The NorthStar OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The NorthStar OCT System can also be linked to other SeaSpine Screw Systems including Mariner, NewPort, Sierra, Atoll, Daytona, Malibu, Mariner MIS, Mariner Outrigger, and Mariner Midline Systems with the use of transitional rods and/or transitional rod connectors.

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

Contact person: Alicia McArthur, Regulatory Affairs Specialist

Date Prepared: December 23, 2019

Device Name

Trade Name: NorthStar™ OCT Spinal System

Common Name: Posterior Occipital-Cervical-Thoracic System

Classification Name: Posterior Cervical Screw System (21 CFR 888.3075)

Class: II

Product Code: NKG, KWP

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K090565	KWP	ELLIPSE™ Occipito-Cervico-Thoracic Spinal System	Globus Medical Inc.
Additional Predicate Devices			
K083863	KWP, MNI, MNH	Atoll™ OCT Spinal System	SeaSpine Orthopedics Corporation (formerly Theken Spine, LLC)
K080526	KWP	Sierra™ Spinal System	SeaSpine Orthopedics Corporation

Device Description

The NorthStar™ OCT System is a spinal fixation system intended to improve the stability of the occipital, cervical, and thoracolumbar areas of the spine.

The NorthStar™ OCT System consists of screws, hooks, rods, offset connectors, set screws, cross connectors, transition implants, occipital plates and associated instruments. Implant components are available in a variety of sizes and can be constructed into a variety of configurations to suit the individual pathology and anatomical conditions of the patient. The scope of this submission includes indication for the use of bone screws in the occipital, cervical spine (C1-C7), and upper thoracic spine (T1-T3).

The implants are manufactured from medical grade titanium alloy and cobalt chrome.

Indications for Use

The NorthStar™ OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, cervical spine (C1-C7) and upper thoracic spine (T1-T3):

- Traumatic spinal fractures and/or traumatic dislocations;
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The NorthStar™ OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The NorthStar™ OCT System can also be linked to other SeaSpine® Screw Systems including Mariner™, NewPort™, Sierra™, Atoll™, Daytona™, Malibu™, Mariner™ MIS, Mariner Outrigger™, and Mariner Midline™ Systems with the use of transitional rods and/or transitional rod connectors.

Summary of Technological Characteristics

The NorthStar™ OCT System was shown to be substantially equivalent and have equivalent technological characteristics to the cited predicate and reference devices in regard to components, device description, intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical).

Non-Clinical Testing

The NorthStar™ OCT System demonstrated similar performance to the predicate systems through static and dynamic axial compression, and static and dynamic torsion testing with reference to ASTM F2706.

Clinical Testing

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

Conclusions

The submitted data demonstrates that the NorthStar™ OCT System has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.