SeaSpine Orthopedics Corporation
Mr. Jesse Albright
Manager, Regulatory Affairs
5770 Armada Dr.
Carlsbad, California 92008

August 3, 2023

Re: K231654
Trade/Device Name: NorthStar OCT System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: June 5, 2023
Received: June 6, 2023

Dear Mr. Jesse Albright:

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,

Eileen Cadel -S Digitally signed by Eileen Cadel -S Date: 2023.08.03 17:04:39 -04'00' for

Colin O'Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231654

Device Name

NorthStar OCT 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 and 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 FDA-cleared SeaSpine/Orthofix screw 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.

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510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation

Address: 5770 Armada Drive, Carlsbad, CA 92008

Phone number: (760) 216-5176

Fax number: (760) 683-6874

Contact Person: Jesse Albright, Manager, Regulatory Affairs

Date Prepared: June 5, 2023

Device Name

Trade Name: NorthStar OCT System

Common Name: Posterior Cervical Screw System
Spinal Interlaminal Fixation System

Classification Name: Posterior Cervical Screw System (21 CFR 888.3075)
Appliance, Fixation, Spinal Interlaminal (21 CFR 888.3050)

Product Code(s): NKG, KWP

Device Class: 2

Legally Marketed Predicate Devices

510(k) Number	Product Code(s)	Trade Name(s)	Manufacturer
Primary Predicate Device			
K193615	NKG; KWP	NorthStar OCT System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K080526	KWP	Sierra OCT System	SeaSpine Orthopedics Corporation

Device Description

The NorthStar OCT System is a posterior occipital cervical thoracic (OCT) system that consists of implants and the associated instruments used to build constructs within the body to act as a temporary or permanent posterior fixation system to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusion to occur. The system

includes a variety of non-sterile, single-use implants manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136), commercially pure titanium (Grade 2 per ASTM F67), and/or cobalt chrome alloy (Co-28Cr-6Mo per ASTM F1537) and is comprised of polyaxial screws, rods, hooks, connectors, occipital plates, occipital screws, and set screws that can be rigidly locked together in a variety of configurations.

The NorthStar OCT System includes the associated instruments that are designed to facilitate the placement, adjustment, final locking, and removal, if necessary, of the system implants. The implants and instruments are provided in trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

Intended Use/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,
- Instability or deformity,
- Failed previous fusion (e.g., pseudoarthrosis),
- Tumors involving the cervical/thoracic spine,
- Degenerative disease, including intractable radiculopathy and/or myelopathy and 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 FDA-cleared SeaSpine/Orthofix screw systems with the use of transitional rods and/or transitional rod connectors.

Summary of Technological Characteristics

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

Non-Clinical Testing

The NorthStar OCT System demonstrated substantially equivalent mechanical performance to the predicate systems through dynamic compression bending, static compression bending, static torsion, and dynamic torsion testing per ASTM F2706.

Clinical Testing

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

Conclusions

The submitted data demonstrate that the NorthStar OCT System is substantially equivalent to the cited legally marketed predicates.