June 18, 2025

SeaSpine Orthopedics Corporation
Sali Gully
Regulatory Affairs Manager
5770 Armada Drive
Carlsbad, California 92008

Re: K250908
Trade/Device Name: Virata Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, OLO
Dated: March 26, 2025
Received: March 26, 2025

Dear Sali Gully:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250908

Please provide the device trade name(s).

Virata Spinal Fixation System

Please provide your Indications for Use below.

The intended use of the Virata Spinal Fixation System in a posterior or anterolateral approach is to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following 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,
- pseudarthrosis, and/or
- failed previous fusion.

When used for posterior non-cervical screw fixation in pediatric patients, the Virata Spinal Fixation System is also indicated as adjunct to fusion to treat:
- Adolescent Idiopathic Scoliosis (AIS)
- Neuromuscular scoliosis
- Congenital scoliosis

The Virata Spinal Fixation System can be used with components of the Mariner and Malibu Systems such as rods and connectors. The Virata Spinal Fixation System is intended to be used with autograft or allograft.

Virata Spinal Fixation Navigated Instruments
The Virata Spinal Fixation Navigated Instruments are intended to be used in the preparation and placement of Virata screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR § 807.92, the following summary of information is provided:

A. Submitted by

Sali Gully
Regulatory Affairs Manager
SeaSpine Orthopedics Corporation
5770 Armada Drive, Carlsbad CA
(760) 216-5176

Date Prepared: May 21st, 2025

B. Device Name

Tade or Proprietary Name:	*Virata Spinal Fixation System*
Common or Usual Name:	Pedicle Screw System
Classification Name(s):	Thoracolumbosacral Pedicle Screw System Spinal Intervertebral Body Fixation Orthosis Stereotaxic Instrument
Device Class:	Class II
Regulation Number(s):	21 CFR § 888.3070 , 21 CFR § 888.3060, CFR § 882.4560
Product Code(s):	NKB, KWP, OLO

C. Legally Marketed Predicate Devices

510(k) Number	Product Code(s)	Trade Name	Manufacturer
Primary Predicate			
K222110	NKB, KWP, KWQ	SeaSpine Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation
Additional Predicate Device(s)			
K132014	NKB, KWP, KWQ, MNH, MNI	NuVasive GSB Global Spinal Balance System	NuVasive, Inc.
K172517	OLO	SeaSpine Navigation Instruments	SeaSpine Orthopedics Corporation

D. Device Description

The Virata Spinal Fixation System is a pedicle screw-based system that utilizes modular and preassembled screws. The modular screw shanks and the shanks of the preassembled screws are available in solid and cannulated configurations, in a variety of length and diameter size options. The rods are provided in a variety of lengths, diameters, and material options in both

straight and pre-contoured configurations that can also be bent with instrumentation to more optimally accommodate the anatomy.

The Virata Spinal Fixation System consists of single-use implants intended to build constructs within the body to act as a temporary or permanent posterior, non-cervical pedicle fixation system, or an anterolateral fixation system to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusions to occur.

Screws are placed in the pedicles of the vertebral body using a posterior approach. The construct is connected using rods to span across screws implanted at various levels. The construct is secured using a set screw tightened to a predetermined torque value which is threaded into the top of the screw to secure the rod. All modular tulips and the tulips of preassembled screws of the system are designed to accept a rod through the opening in the top of the tulip, except the closed polyaxial modular tulip and the tulip of closed preassembled screws for which the rod is passed through an opening on the side of the tulip. The Virata Spinal Fixation System implants are manufactured from titanium alloy Ti-6Al-4V ELI (per ASTM F136), and cobalt chrome alloy (Co-28Cr-6Mo per ASTM F1537).

The system includes the associated non-sterile instruments that facilitate the placement, adjustment, and removal, if necessary, of the system implants as well as trays and caddies that may be used for storage, protection, and organization prior to and during the steam sterilization process for the non-sterile components. Non--sterile instruments also include instrumentation compatible with navigation arrays to allow for navigated implant placement.

E. Indications for Use

Virata Spinal Fixation System

The intended use of the *Virata Spinal Fixation System* in a posterior or anterolateral approach is to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following 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,
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F. Technological Characteristics

The *Virata Spinal Fixation System* is identical or similar to the cited predicate devices in regard to components, device description, intended use/indications for use, technological characteristics (e.g., operating principle, design, materials, manufacturing, etc.) and performance (mechanical safety).

G. Performance Data

The purpose of this submission is to introduce the *Virata Spinal Fixation System*. Mechanical performance testing was conducted to assess the safety and compatibility of the subject device. The following testing was performed:

- F1717 Dynamic Compression Bending
- F1717 Static Compression Bending
- F1717 Static Torsion
- F1798 Static Anterior-Posterior Load (F_x)
- F1798 Static Anterior-Posterior Load (F_x) at Max-Angle

The results of these studies demonstrate that the subject *Virata Spinal Fixation System* is substantially equivalent to legally marketed devices.

H. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *Virata Spinal Fixation System* has been shown to be substantially equivalent to the legally marketed predicate devices.