

October 29, 2026

SeaSpine Orthopedics Corporation
Nathan Wright
Senior Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K262574
Trade/Device Name: Convoy Expandable Corpectomy System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: September 30, 2026
Received: October 1, 2026

Dear Nathan Wright:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

BRENT SHOWALTER -S

Brent Showalter, Ph.D.
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.	K262574

Please provide the device trade name(s).

Convoy Expandable Corpectomy System

Please provide your Indications for Use below.

The Convoy Expandable Corpectomy System is indicated for vertebral body replacement in the cervical spine (C2-T1) and the thoracolumbar spine (T1-L5). The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the cervical spine (C2-T1), the Convoy Expandable Corpectomy System is intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor fracture or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in the cervical degenerative disorders. These spacers are 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, with bone graft used at the surgeon's discretion. The System is intended to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine.

When used in the thoracolumbar spine (T1-L5), the Convoy Expandable Corpectomy System is intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The system is intended to be used with supplemental fixation that has been cleared by the FDA for use in the thoracolumbar spine (i.e. posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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

Applicant Name: SeaSpine Orthopedics Corporation
Address: 5770 Armada Drive
Carlsbad, California 92008
Phone Number: 619-212-4143
Contact Person: Nathan Wright, Senior Regulatory Affairs Specialist

Date Prepared: July 24, 2026

B. Device Name

Tade or Proprietary Name: Convoy Expandable Corpectomy System
Common or Usual Name: Spinal Vertebral Body Replacement Device
Classification Name(s): Spinal Intervertebral Body Fixation
Device Class: Class II
Regulation Number(s): 21 CFR § 888.3060
Product Code(s): MQP, PLR

C. Legally Marketed Predicate Devices

510(k) #	Product Code(s)	Trade Name	Manufacturer
Primary Predicate			
K233359	MQP, PLR	Dominion Expandable Corpectomy System	Astura Medical
Additional Predicate Device(s)			
K070381	MQP	Vu Mesh VBR System	Theken Spine
K202637	MQP, PLR	F3D Corpectomy System	CoreLink LLC
Reference Predicate Device(s)			
K250908	NKB, KWP, OLO	Virata Spinal Fixation System	SeaSpine Orthopedics Corporation
K212904	OVE, ODP	SeaSpine WaveForm C Interbody System	SeaSpine Orthopedics Corporation

D. Device Description

The Convoy Expandable Corpectomy System is a vertebral body replacement device comprised of an Expandable Core, Endplate Set Screws, and Modular Endplates. The Expandable Core provides mechanical support to the vertebral column until fusion across the treated levels occurs. The Expandable Core may be used in the unexpanded state, in the partially expanded state, or in the fully expanded state and is adjusted to achieve the height requirements of the patient anatomy. The Modular Endplates provide contact to the adjacent vertebral endplates; offered in various footprints and lordotic options, the Modular Endplates which best accommodate the anatomical requirements of the patient are attached to the Expandable Core during

the surgery. An Endplate Set Screw locks each Modular Endplate to the Expandable Core. The system is offered in a variety of sizes and lordotic options to suit individual pathology and anatomical conditions of the patient. The Convoy Expandable Corpectomy System be packed with autograft or allograft prior to implantation and is intended for use with supplemental fixation.

The subject implants are manufactured from biocompatible medical grade titanium alloy; the Expandable Core assemblies and the Endplate Set Screws are machined from Ti-6Al-4V ELI per ASTM F136, and the Modular Endplates are additively manufactured from Ti-6Al-4V ELI per ASTM F3001. The Expandable Core and Endplate Set Screws are offered non-sterile. The non-sterile implants and accessory instrumentation are designed to be sterilized by the end user before each use. The Modular Endplates are offered gamma sterilized. The Convoy Expandable Corpectomy System includes instruments and implants designed to facilitate the placement of the system through an anterior approach for cervical placement or through an anterior or anterolateral approach for thoracolumbar placement.

E. Indications for Use

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F. Technological Characteristics

The Convoy Expandable Corpectomy 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 Convoy Expandable Corpectomy System. Mechanical performance testing was conducted to assess the safety and compatibility of the subject device. The following testing was performed:

- F2077 Static and Dynamic Axial Compression
- F2077 Static and Dynamic Torsion
- ASTM F1877 Particulate Analysis
- ASTM F2267 Subsidence
- Expulsion

The results of these studies demonstrate that the subject Convoy Expandable Corpectomy 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 Convoy Expandable Corpectomy System has been shown to be substantially equivalent to the legally marketed predicate devices.