August 26, 2026

Wenzel Spine, Inc.
Erik Emstad
Chief Technical Officer
2535 Brockton Dr.
Suite 450
Austin, Texas 78758

Re: K262595
Trade/Device Name: VariLift-C Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: July 27, 2026
Received: July 27, 2026

Dear Erik Emstad:

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 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 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,

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.	K262595

Please provide the device trade name(s).

VariLift-C Cervical Interbody Fusion System

Please provide your Indications for Use below.

The Wenzel Spine VariLift-C Interbody Fusion System is indicated for use in skeletally mature patients with cervical disc degeneration (DDD) and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI) that results in radiculopathy, myelopathy, and/or pain at one or multiple contiguous levels from C2/C3 to C7/T1. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The Wenzel Spine VariLift-C Interbody Fusion System is used to facilitate intervertebral body fusion in the cervical spine and is placed in a unilateral or a bilateral fashion via an anterior approach using autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The Wenzel Spine VariLift-C Interbody Fusion System is to be used with or without supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

Please select the types of uses (select one or both, as applicable).	☒ 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

Device Trade Name:	VariLift-C Interbody Fusion System
Manufacturer:	Wenzel Spine, Inc. 2535 Brockton Drive, Suite 450 Austin, TX 78758
Contact:	Erik Emstad CTO Wenzel Spine, Inc.
Date Prepared:	July 22, 2026
Panel:	Orthopedic
Class:	II
Product Codes:	ODP
Regulation:	21 CFR 888.3080
Primary Predicate:	VariLift-C Interbody Fusion System, (K231076)
Reference Device:	BAK/C, (P980048, K143297)

Indications For Use:
The Wenzel Spine VariLift-C Interbody Fusion System is indicated for use in skeletally mature patients with cervical disc degeneration (DDD) and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI) that results in radiculopathy, myelopathy, and/or pain at one or multiple contiguous levels from C2/C3 to C7/T1. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The Wenzel Spine VariLift-C Interbody Fusion System is used to facilitate intervertebral body fusion in the cervical spine and is placed in a unilateral or a bilateral fashion via an anterior approach using autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. When used at one disc level, the Wenzel Spine VariLift-C interbody Fusion System may be used with or without supplemental fixation. When used at multiple contiguous levels, the Wenzel Spine VariLift-C Interbody Fusion System is intended to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

Device Description:
The VariLift® Cervical Interbody Fusion device (VariLift-C) is a self-tapping, expandable device with an interior sliding wedge. VariLift-C is cylindrical-ovoid in shape, which is adapted to the general shape of the vertebral endplates. The grooved and fluted fusion device has fenestrations (graft windows) positioned between each of its four quadrants to allow bony ingrowth and contact with the endplates. The device is manufactured from medical grade titanium alloy (Ti6Al4V) per ASTM F136.

The purpose of this submission is to add large implant sizes.

Comparison of Technological Characteristics:
The subject device incorporates a similar design, same materials and same indications for use as the predicate device. The differences in design do not raise different questions of safety and effectiveness and the performance testing conducted demonstrates substantial equivalence.

Performance Testing:
The substantial equivalence of the VariLift-C interbody Fusion Device to the predicate devices is evidenced by having the same intended use, Indications for Use, material, principles of operation, and fundamental technology.

Substantial Equivalence:
The data presented within the subject 510(k) demonstrates that the VariLift-C Interbody Fusion System is substantially equivalent to the cited predicate device. The subject and predicate have the same intended use, have the same fundamental scientific technology, and are manufactured from the same material.

Conclusion:
Based on the indications for use, technological characteristics, performance testing and comparison to the predicate device and reference device, the VariLift-C Interbody Fusion System is as safe and effective as the legally marketed predicate device.