September 27, 2023

Wenzel Spine, Inc.
℅ Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
MCRA
803 7th Street, NW
Washington, District of Columbia 20001

Re: K231076
Trade/Device Name: VariLift®-C Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: August 9, 2023
Received: August 9, 2023

Dear Justin Eggleton:

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.

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,

Katherine D. Kavlock -S

for
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

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.

510(k) Number *(if known)*
K231076

Device Name
VariLift®-C Interbody Fusion System

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Trade Name:	VariLift®-C Interbody Fusion System
Manufacturer:	Wenzel Spine, Inc. 1130 Rutherford Ln #200 Austin, TX 78753
Prepared by:	Justin Eggleton MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800 jeggleton@mcra.com
Date Prepared:	September 25, 2023
Classifications:	21 CFR §888.3080
Classification Name:	Intervertebral body fusion device
Common Name:	Intervertebral Fusion Device With Bone Graft, Cervical
Class:	II
Product Codes:	ODP
Primary Predicate:	K222276, CONDUIT™ Cervical Cage
Additional Predicate:	K180822, VariLift® -C Interbody Fusion System

Indications For Use:
The Wenzel Spine VariLift Cervical 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 Cervical 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.

Predicate Device:
Wenzel Spine, Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, VariLift-C Interbody Fusion System is substantially equivalent in indications, design principles, and performance to the following predicate devices:

Primary Predicate

Manufacturer	Device Name	510(k) number
DePuy Spine	CONDUIT™ Cervical Cage	K222276

Additional Predicate:

Manufacturer	Device Name	510(k) number
Wenzel Spine, Inc.	VariLift-LX Interbody Fusion System, VariLift-C Interbody Fusion System	K180822

Performance Testing Summary:
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.

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. VariLift-C Interbody Fusion System is as safe, and as effective, compared to the predicate devices.