August 5, 2021

Wenzel Spine, Inc.
Erik Emstad
VP of Product Development
1130 Rutherford Lane, Suite 200
Austin, Texas 78753

Re: K180822
Trade/Device Name: VariLift®-LX Interbody Fusion System, VariLift®-C Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP

Dear Erik Emstad:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter sent January 28, 2019. Specifically, FDA is updating this SE Letter because incorrect SE elements were emailed in the original communication.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Brent Showalter, Ph.D., OHT6: Office of Orthopedic Devices, (240) 402-1840, Brent.Showalter@fda.hhs.gov.

Sincerely,

Brent Showalter -S

Brent L. 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

August 5, 2021

Wenzel Spine, Inc.
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VP of Product Development
1130 Rutherford Lane, Suite 200
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Re: K180822
Trade/Device Name: VariLift®-LX Interbody Fusion System, VariLift®-C Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: January 11, 2019
Received: January 15, 2019

Dear Erik Emstad:

This letter corrects our substantially equivalent letter of January 28, 2019.

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,

Brent Showalter -S

Brent L. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180822

Device Name
VariLift®-C Interbody Fusion System

Indications for Use *(Describe)*
The Wenzel Spine VariLift® Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level.

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 at the C3 to C7 disc levels using autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The Wenzel Spine VariLift Cervical Interbody Fusion System may 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180822

Device Name
VariLift®-LX Interbody Fusion System

Indications for Use *(Describe)*
The Wenzel Spine VariLift® Interbody Fusion System (VariLift®-L/LX and VariLift®-A) is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

VariLift®-L/LX is designed to be implanted bi-laterally via a posterior (PLIF) approach or as a single device via a transverse (TLIF) approach. VariLift®-L/LX may be implanted with or without supplemental fixation and is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. VariLift®-A is designed to be implanted bi-laterally via an anterior (ALIF) approach. VariLift®-A may be implanted with or without supplemental fixation and is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	January 25, 2019
Applicant/Sponsor:	Wenzel Spine, Inc. 1130 Rutherford Lane, Suite 200 Austin, TX 78753
Contact Person:	Erik Emstad Vice President of Product Development Phone : 952-221-3213 Fax : 512-469-0604 Email : eemstad@wenzelspine.com
Trade Name:	VariLift®-LX Interbody Fusion System
Common Name:	Interbody Fusion Device (MAX)
Device Class:	Class II
Classification Name:	MAX, 888.3080 – Intervertebral Fusion Device with Bone Graft, Lumbar
Device Panel:	Orthopedic
Trade Name:	VariLift®-C Interbody Fusion System
Common Name:	Intervertebral Body Fusion Device (ODP)
Device Class:	Class II
Classification Name:	ODP, 888.3080 – Intervertebral Fusion Device with Bone Graft, Cervical
Device Panel:	Orthopedic

Device Description & Technological Characteristics

VariLift-LX Interbody Fusion Device

The VariLift-LX is a self-tapping, expandable device with an interior sliding wedge and a posterior end cap. The devices are cylindrical-ovoid in shape, which is adapted to the general shape of the vertebral endplates. The VariLift-LX devices are made of titanium alloy (Ti6AI4V ELI per ASTM F136) and are provided sterile. The VariLift-LX Interbody Fusion Device may be implanted bi-laterally via a posterior lumbar (PLIF) approach or as a single device via a transverse (TLIF) approach.

VariLift-C Interbody Fusion Device

The Wenzel Spine VariLift Cervical Interbody Fusion System is a self-tapping, expandable device with an interior sliding wedge. The devices are cylindrical-ovoid in shape, which is adapted to the general shape of the vertebral end plates. All components are composed of Titanium-6A1-4V ELI alloy that conforms to ASTM F136. The VariLift Cervical device is grooved and fluted with large fenestrations (graft windows) positioned between each of its four quadrants that provide bony contact with the endplates. The device is supplied sterile.

Indications for Use

VariLift-LX Interbody Fusion Device

The Wenzel Spine VariLift® Interbody Fusion System (VariLift®-L/LX and VariLift®-A) is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous

levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

VariLift®-L/LX is designed to be implanted bi-laterally via a posterior (PLIF) approach or as a single device via a transverse (TLIF) approach. VariLift®-L/LX may be implanted with or without supplemental fixation and is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. VariLift®-A is designed to be implanted bi-laterally via an anterior (ALIF) approach. VariLift®-A may be implanted with or without supplemental fixation and is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

VariLift-C Interbody Fusion Device
The Wenzel Spine VariLift® Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level.

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 at the C3 to C7 disc levels using autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The Wenzel Spine VariLift Cervical Interbody Fusion System may 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.

Predicate Devices
VariLift-LX Interbody Fusion Device
Primary Predicate: VariLift®-L Interbody Fusion Device, K151900
Additional Predicate: Amendia Interbody Fusion Devices, K160924

VariLift-C Interbody Fusion Device
Primary Predicate: VariLift-C Interbody Fusion Device, K120603
Additional Predicate: Amendia Interbody Fusion Devices, K160924

Summary of Technological Characteristics
VariLift-LX Interbody Fusion Device
The technological characteristics of the subject VariLift-LX Interbody Fusion Device remain the same as, or similar to, the predicate VariLift-L Interbody Fusion Device (K151900) in regards to intended use, Indications for Use, design, manufacturing methods, fundamental technology, materials, and principles of operation.

VariLift-C Interbody Fusion Device
The technological characteristics of the subject VariLift-C Interbody Fusion Device remain the same as, or similar to, the predicate VariLift-C Interbody Fusion Device (K120603) in regards to intended use, Indications for Use, design, manufacturing methods, fundamental technology, materials, and principles of operation.

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Summary of Performance Testing

VariLift-LX Interbody Fusion Device

The substantial equivalence of the VariLift-LX Interbody Fusion Device to the predicate devices is evidenced by having the same, or similar, intended use, Indications for Use, materials, principles of operation, and fundamental technology.

VariLift-C Interbody Fusion Device

The substantial equivalence of the VariLift-C Interbody Fusion Device to the predicate devices is evidenced by having the same, or similar, intended use, Indications for Use, materials, principles of operation, and fundamental technology. Non-clinical testing was conducted on the smallest new size to determine substantial equivalence to the predicate VariLift-C smallest size.

Static compression, compression shear, torsion testing, and dynamic compression testing per ASTM 2077-14: "Test Methods for Intervertebral Body Fusion Devices"; subsidence testing per ASTM F2267-04: "Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression"; and expulsion testing demonstrated that the subject VariLift-C Interbody Fusion Devices are substantially equivalent to the predicate devices in terms of mechanical performance.

Conclusion

VariLift-LX Interbody Fusion Device

Based on the comparison to the predicate devices, the subject VariLift-LX Interbody Fusion Device has been shown to be substantially equivalent to legally marketed predicate devices.

VariLift-C Interbody Fusion Device

Based on the comparison to the predicate devices, the subject VariLift-C Interbody Fusion Device has been shown to be substantially equivalent to legally marketed predicate devices.