



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Wenzel Spine, Incorporated  
Beckinam Nowatzke  
Director, Quality and Regulatory Affairs  
206 Wild Basin Road, Building A, Suite 203  
Austin, Texas 78746

December 11, 2015

Re: K151900

Trade/Device Name: VariLift®-L Interbody Fusion Device  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: November 10, 2015  
Received: November 12, 2015

Dear Ms. Nowatzke:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



## 510(k) Summary

**Date Traditional 510(k) Prepared:** July 7, 2015

**Trade Name:** VariLift®-L Interbody Fusion Device

**Common Name:** Interbody Fusion Device (MAX)

**Classification Name:** MAX 888.3080 – Intervertebral Fusion Device with Bone Graft, Lumbar

**Submitted By:** Wenzel Spine, Inc.  
206 Wild Basin Road, Building A, Suite 203  
Austin, TX 78746

**Contact Name:** Beckinam Nowatzke  
Director, Quality & Regulatory Affairs  
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### Predicate Device

VariLift®-L Interbody Fusion Device, K100820 (Primary Predicate).  
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

### Description of Device:

The VariLift®-L Interbody Fusion Device may be implanted bi-laterally via a posterior lumbar (PLIF) approach or as a single device via a transverse (TLIF) approach. The VariLift®-L 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®-L devices are made of titanium alloy (Ti6Al4V ELI per ASTM F136) and are provided sterile.

A design change was made on all sizes of the VariLift®-L devices to increase the surface in contact at the superior and inferior vertebrae. Additionally dimensional modification were made to the instrumentation to ensure all instruments work with all sizes of the modified devices.

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**Indications for Use:**

The Wenzel Spine VariLift® Interbody Fusion System (VariLift®-L 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 is designed to be implanted bi-laterally via a posterior (PLIF) approach or as a single device via a transverse (TLIF) approach. VariLift®-A is designed to be implanted bi-laterally via an anterior (ALIF) approach. VariLift®-L and VariLift®-A may be implanted with or without supplemental fixation and is intended for use with autograft to facilitate fusion.

**Technical Characteristics:**

The VariLift®-L is a self-tapping, expandable Interbody Fusion Device with an interior sliding wedge and a posterior end cap. The device is grooved and fluted with large fenestrations (graft windows) positioned between each of the four quadrants that provide bony contact with the endplates.

**Legally Marketed Predicate Devices and Substantial Equivalence:**

The proposed VariLift®-L Interbody Fusion Device is substantially equivalent to the primary predicate VariLift®-L cleared as part of the VariLift® Interbody Fusion System (K100820, August 5, 2010) in terms of technology, design, and intended use. Additional predicate devices include down-classified cages and other cleared Interbody fusion devices such as the Brantigan Lumbar I/F Cage (P960025).

**Summary of Non-Clinical Performance Testing:**

Additional Device Sizes: Non-clinical testing was conducted on the smallest and longest of the new proposed sizes (10x28mm) to determine substantial equivalence to the primary predicate VariLift®-L smallest size (11x24mm). Static compression, shear, and dynamic axial testing (per ASTM 2077: "Test methods for Intervertebral Body Fusion Devices"), subsidence testing (per ASTM F2267: "Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression."), and expulsion testing (per ASTM Draft Standard F-04.25.02.02, "Static Push-out Test Method for Intervertebral Body Fusion Devices," Draft #2 – August 29, 2000) demonstrated that the subject VariLift®-L Interbody Fusion Devices are substantially equivalent to predicate devices in terms of mechanical performance.

Design Modifications to Existing Sizes: Non-clinical testing was conducted on the smallest and longest of the proposed new sizes (10x28mm) to determine substantial equivalence to the primary predicate VariLift®-L smallest size (11x24mm). Static compression, shear, and dynamic

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axial testing (per ASTM 2077: “Test methods for Intervertebral Body Fusion Devices”), subsidence testing (per ASTM F2267: “Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression.”), and expulsion testing (per ASTM Draft Standard F-04.25.02.02, “Static Push-out Test Method for Intervertebral Body Fusion Devices,” Draft #2 – August 29, 2000) demonstrated that the subject VariLift®-L Interbody Fusion Devices are substantially equivalent to predicate devices in terms of mechanical performance.

Design Modification to Instrumentation: Minor modifications to one of the VariLift®-L instruments were made to accommodate the TLIF approach. An engineering analysis was performed to confirm substantial equivalence to previously cleared instrumentation.

**Conclusion:**

The proposed VariLift®-L Interbody Fusion Devices are substantially equivalent to the primary predicate VariLift®-L Interbody Fusion Devices (K100820) in terms of intended use, indications for use, intervertebral body design and fundamental scientific technology.

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