510(k) Summary

Company Name: Wenzel Spine, Inc.
206 Wild Basin Road, Building A, Suite 203
Austin, TX 78746

Contact Name: Sandie Roth
Director of Clinical Affairs
Phone: 512-501-4022
Fax: 512-469-0604

SEP 03 2013

Date Special 510(k) Prepared: May 1, 2013

Trade Name: VariLift-L® Interbody Fusion Device

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Body Fusion Device with Bone Graft, Lumbar (21 CFR 888.8030)

Product Code: MAX

Description of Device:

The Wenzel Spine VariLift Interbody Fusion System is offered in two (2) configurations of various sizes that are designed based on surgical approach, and consist of:

1) VariLift-L®, which may be implanted bi-laterally via a posterior lumbar (PLIF) approach or as a single device via a transverse (TLIF) approach.
2) VariLift-A®, which may be implanted bi-laterally via an anterior (ALIF) approach.

A design change was made on all sizes of the VariLift-L® devices to eliminate the risk of orientation error when loading the implant on the insertion instruments. Additionally, dimensional and threadform modifications were made to the instrumentation to ensure all instruments work with the modified devices.

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 SI, 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 are intended for use with autograft to facilitate fusion.

Technical Characteristics:

The VariLift-L® and VariLift-A® are self-tapping, expandable devices with an interior sliding wedge and a posterior end cap. They are grooved and fluted devices with large fenestrations (graft windows) positioned between each of the four quadrants that provide bony contact with the endplates. The devices are made of titanium alloy (per ASTM F136).

Legally Marketed Predicate Devices and Substantial Equivalence:

The subject VariLift-L® Interbody Fusion Device is substantially equivalent to the predicate 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 BAK Cage (P950002), Ray Threaded Fusion Cage (P950019), Lumbar I/F Cage (P960025), and Perimeter Interbody Fusion Device (K111525, K090353).

Summary of Non-Clinical Performance Testing:

Design Modifications to Existing Sizes: Non-clinical testing was conducted to determine substantial equivalence to the original VariLift-L® design. Static compression, shear and torsion testing and dynamic axial testing (per ASTM 2077: "Test methods for Intervertebral Body Fusion Devices") demonstrated that the subject and predicate VariLift-L® Interbody Fusion devices are substantially equivalent in terms of mechanical performance.

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

Conclusion:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 3, 2013

Wenzel Spine, Incorporated
% Ms. Sandie Roth
Director of Clinical Affairs
206 Wild Basin Road, Building A, Suite 203
Austin, Texas 78746

Re: K131296
Trade/Device Name: VariLift Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 20, 2013
Received: August 22, 2013

Dear Ms. Roth:

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 Part 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

Indications for Use

510(k) Number (if known): K131296

Device Name: VariLift Interbody Fusion System

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 are intended for use with autograft to facilitate fusion.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Caroline Rhim -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131296