510(k) SUMMARY
Wenzel Spine's VariLift-C®

Date: February 10, 2012

Contact:

Sourabh Mishra
Chief Technical Officer
512-501-4017

Wenzel Spine, LLC
206 Wild Basin Road
Building A, Suite 203
Austin, TX 78746

JAN 29 2013

Trade Name: VariLift® Cervical Interbody Fusion Device
Common Name: Intervertebral body fusion device
Product Class: Class II
Classification: 21 CFR §888.3080 Orthosis, intervertebral body fusion device
Product Code: ODP
Panel Code: 87

Name of Device and Name/Address of Sponsor

Wenzel Spine, LLC
206 Wild Basin Road
Building A, Suite 203
Austin, TX 78746
512-501-4017

Device Description
The Wenzel Spine VariLift Cervical Interbody Fusion System is self-tapping, expandable devices 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-6Al-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 in an appropriately labeled sterile packaging.

The instrument case is 10 inch X 20 inch. All instruments for VariLift-C fit on a single tray.

Predicate Devices
The VariLift-C® was shown to be substantially equivalent to legally marketed predicate device. The predicate devices are the VariLift Cervical Interbody Fusion System (K111123) and the BAK/C Interbody Fusion Device (P980048).

SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES
The VariLift Cervical Interbody Fusion System is substantially equivalent to the VariLift-C device previously cleared and the BAK®/C Vista Cage in terms of intended use, design, and materials used. The table below compares the features and characteristics of the VariLift Cervical Interbody Fusion System to these predicate devices.

Items	VariLift Cervical Interbody Fusion System	VariLift Cervical Interbody Fusion System	BAK®/C Vista Interbody Fusion System
Sponsor	Wenzel Spine	Wenzel Spine	Zimmer
510(K) Number	N/A	K111123	P980048 S003
Indications for Use	Per FDA Guidance	Per FDA Guidance	Per FDA Guidance
Material	Ti-6Al-4V alloy per ASTM F136	Ti-6Al-4V alloy per ASTM F136	PEEK Optima LT1
Implant Levels	One Level	One Level	One Level
# Implants per level	Single or Pairs	Single or Pairs	Single or Pairs
Supplemental Fixation	With or Without Supplemental Fixation	With Supplemental Fixation	With or Without Supplemental Fixation

Intended Use / Indications for Use

The Wenzel Spine VariLift® Cervical Interbody Fusion System is indicated 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 bone. 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.

Performance Data

Whereas the only change submitted for this Premarket Notification is a change in the Indications for Use, no new performance data is being submitted.

Summary:

The VariLift-C Interbody Fusion Device and predicate devices have the same intended use, to provide mechanical stability in the cervical disc space to facilitate biologic fusion. The indications for use of the VariLift-C Interbody Fusion Device are exactly the same as one of the predicate devices. Moreover, the device is very similar in its size to the predicate device. The materials used are also the same as in the predicate device. There are no significant differences in technological characteristics compared to the predicate devices, and the minor differences that do exist do not raise any new types of safety or efficacy issues. Furthermore, clinical data presented demonstrates that these differences do not adversely impact device performance, as discussed below.

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

January 29, 2013

Wenzel Spine, LLC
% Mr. Sourabh Mishra
Chief Technical Officer
206 Wild Basin Road
Building A, Suite 203
Austin, Texas 78746

Re: K120603
Trade/Device Name: VariLift-C®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 8, 2013
Received: January 11, 2013

Dear Mr. Mishra:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K120603
Device Name: VariLift-C®

Indications for Use:

The Wenzel Spine VariLift® Cervical Interbody Fusion System is indicated 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.

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

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Stephanie Bechtold -S
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K120603