K111123

DEC - 8 2011

Wenzel Spine VariLift Cervical Interbody Fusion System

510(k) Summary of Safety and Effectiveness

SUBMITTED BY

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

ESTABLISHMENT REGISTRATION NUMBER

3008009850

CONTACT PERSON

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SUBMISSION PREPARED BY

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DATE PREPARED

April 12, 2011

CLASSIFICATION NAME

ODP 888.3080 – Intervertebral Fusion Device with Bone Graft, Cervical

COMMON NAME

Intervertebral Body Fusion Device

PROPRIETARY NAME

VariLift Interbody Fusion System (VariLift-C)

IDENTIFICATION OF PREDICATES

BAK®/C Vista Cage (P980048 S003)
BAK®/Cervical Interbody Fusion (P980048)
LDR Interbody Fusion System (K091088)

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.

k111123

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.

SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

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

INDICATIONS:

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

DISCUSSION OF NON-CLINICAL TESTING

The following non-clinical tests were conducted:

- Static and dynamic compression testing, conducted in accordance with ASTM F2077-03
- Static shear testing, conducted in accordance with ASTM F2077-03
- Static and dynamic torsion testing, conducted in accordance with ASTM F2077- 03
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02

K111123

CONCLUSIONS

The subject and predicate devices share the same intended use, implant design and material of manufacture. The non-clinical test results demonstrate that any minor differences do not impact device performance as compared to the predicates. The non-clinical and clinical test results demonstrate that the VariLift Cervical Interbody Fusion System is substantially equivalent to the predicate devices and support the use of VariLift-C with supplemental fixation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Wenzel Spine
% The OrthoMedix Group, Inc.
Mr. J. D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

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Re: K111123
Trade/Device Name: Wenzel Spine VariLift Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: November 9, 2011
Received: November 14, 2011

Dear Mr. Webb:

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
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111123

INDICATIONS FOR USE

510(k) Number (if known): K111123

Device Name: **Wenzel Spine VariLift Cervical Interbody Fusion System**

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111123

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