Wenzel Spine VariLift Interbody Fusion System (VariLift-L and VariLift-A)

510(k) Summary of Safety and Effectiveness

SUBMITTED BY

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

AUG 05 2010

ESTABLISHMENT REGISTRATION NUMBER

3008009850

CONTACT PERSON

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SUBMISSION PREPARED BY

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QA Consulting, Inc.
Phone: 512-507-0746

DATE PREPARED

March 10, 2010

CLASSIFICATION NAME

MAX 888.3080- Intervertebral Fusion Device with Bone Graft, Lumbar

COMMON NAME

Intervertebral Body Fusion Device (MAX)

PROPRIETARY NAME

VariLift Interbody Fusion System (VariLift-L and VariLift-A)

IDENTIFICATION OF PREDICATES

- BAK® Cage (P950002)
- RAY® Threaded Fusion Cage (P950019)
- Lumbar I/F Cage (P960025)
- Asfora Bullet Cage System (K090048)
- Paramount (K072120)
- L-Varlock (K080537).

DEVICE DESCRIPTION

The proposed Wenzel Spine VariLift Interbody Fusion System will be offered in two (2) configurations of various sizes that are designed based on indicated spinal implant level and 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.

The VariLift-L and VariLift-A are grooved and fluted devices with large fenestrations (graft windows) positioned between each of its four quadrants that provide bony contact with the endplates. The VariLift-L and VariLift-A are self-tapping, expandable devices 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 end plates. All components are composed of Titanium-6Al-4V ELI alloy that conforms to ASTM F136.

INDICATIONS:

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.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The purpose of this premarket notification is to obtain clearance to market the Wenzel Spine VariLift Interbody Fusion System (VariLift-L and VariLift-A), which may be implanted with or without supplemental fixation and is intended for use with autograft to facilitate fusion. 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.

The VariLift-L and VariLift-A are self-tapping, expandable devices 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 end plates. All components are composed of Titanium-6Al-4V ELI alloy that conforms to ASTM F136.

The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics support this conclusion:

- 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
- Threaded and expandable implant design
- Implant material: Titanium-6Al-4V ELI alloy that conforms to ASTM F136
- Substantially equivalent results of non-clinical testing relative to static and dynamic testing (per ASTM F2077-03), subsidence (per ASTM F2267-04), and expulsion (per ASTM Draft Standard F-04.25.02.02).

- Substantially equivalent results of clinical testing, conducted solely without supplemental fixation.

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
- Dynamic torsion testing, conducted in accordance with ASTM F2077-03
- Subsidence testing, conducted in accordance with ASTM F2267-04
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02

DISCUSSION OF CLINICAL TESTING
Clinical data were also submitted, the results of which demonstrate that the Wenzel Spine VariLift Interbody Fusion System is substantially equivalent to the predicate(s). The clinical trial was conducted solely without the use of supplemental fixation.

CONCLUSIONS
The subject and predicate devices share the same intended use, implant design and material of manufacture. The non-clinical and 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 System is substantially equivalent to the predicate devices and support the use of VariLift with or without 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

AUG 05 2010

Wenzel Spine
% Sourabh Mishra, Ph.D.
Chief Technology Officer
206 Wild Basin Road
Building A, Suite 203
Austin, Texas 78746

Re: K100820
Trade/Device Name: Wenzel Spine VariLift Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 14, 2010
Received: July 23, 2010

Dear Dr. 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.

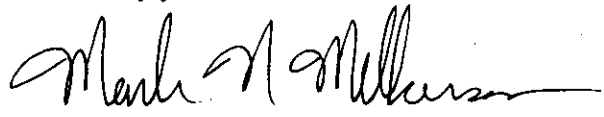
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

AUG 05 2010

510(k) Number (if known): K100820

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

Indications for Use:

The Wenzel SpineVariLift 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.

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 K100820

Wenzel Spine

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