



Food and Drug Administration  
10903 New Hampshire Avenue  
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VGI Medical, LLC  
% Rich Jansen, Pharm.D.  
Consultant  
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11821 Bramble Cove Drive  
Fort Myers, Florida 33905

January 13, 2016

Re: K151312

Trade/Device Name: VerteLP Interbody Fusion Device  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: OVD  
Dated: December 11, 2015  
Received: December 14, 2015

Dear Dr. Jansen:

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 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

## Indications for Use

510(k) Number (if known)  
K151312

Device Name  
VerteLP Interbody Fusion Device

### Indications for Use (Describe)

The VerteLP is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-L5. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is intended to be used with supplemental fixation in addition to the integrated fixation jaws, and must be used with autograft bone.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) Summary

**Date Prepared:** January 12, 2016

**Contact:** Tov Vestgaarten, Ph.D. President  
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**Regulatory Contact:** Rich Jansen, Pharm. D.  
Silver Pine Consulting, LLC  
richj@s-pineconsulting.com

**Trade Name:** VerteLP Interbody Fusion Device  
**Product Class:** Class II  
**Classification:** 21 CFR §888.3080  
**Common Name:** Intervertebral Body Fusion Device  
**Product Codes:** OVD  
**Panel Code:** 87

### Indications for Use:

The VerteLP is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-L5. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is intended to be used with supplemental fixation in addition to the integrated fixation jaws, and must be used with autograft bone.

### Device Description:

The VerteLP implant is an Intervertebral Body Fusion Device (IBFD) intended to be used in the lumbar spine via a lateral surgical approach. It is intended to stabilize a spinal segment to promote fusion between adjacent vertebral bodies. It also provides indirect decompression to relieve constricted nerve roots. Center apertures have been designed into the VerteLP implant for placement of bone graft to promote fusion through the center of the implant. The device has integrated fixation in the form of laterally- locking jaws to facilitate additional stability.

VerteLP is available in a variety of sizes and shapes in order to better accommodate each patient's unique anatomy. The implant is made from Ti6Al4V alloy per ASTM F-136, Zeniva PEEK ZA-500 per ASTM F2026, UHMWPE per ASTM F648 and tantalum per ASTM F560.

The devices are available in two widths, heights from 7-17mm and in both parallel and lordotic shapes to accommodate varied patient's anatomy.

**Predicate Device(s):**

The VGI VerteLP is substantially equivalent to the Primary Predicate device, the Coroent XL-F from Nuvasive (K140479). Additional predicate devices include the Avenue L device from LDR (K113285) and the Intercontinental device from Globus (K103382).

**Performance Standards:**

Mechanical testing was completed by an independent laboratory, Orthokinetic Testing Technologies, following ASTM F2077-14 and F2267-04. Testing was conducted on the worst case implant for each test completed and included the following:

Static Compression  
Static Compression Shear  
Static Torsion  
Subsidence  
Dynamic Compression  
Dynamic Compression Shear

**Technological Characteristics:**

The VerteLP device is similar in sizes, materials, function and indications for use as the predicate devices. One feature that the VerteLP device has that is different than the predicate devices is the method of fixing the device to the superior and inferior vertebral bodies to minimize any chance of implant migration.

**Conclusion:**

VGI Medical, LLC concludes that the VerteLP device is substantially equivalent to the predicate devices and that the minor differences do not raise any new questions of safety or efficacy.