DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 31, 2015

Zimmer Spine, Incorporated
Mr. Jonathan Gilbert
Associate Director, Regulatory Affairs
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K150896
Trade/Device Name: Vitality® Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: July 31, 2015
Received: August 3, 2015

Dear Mr. Gilbert:

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" (21 CFR 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,

Lori A. Wiggins -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K150896

Device Name
Vitality® Spinal Fixation System

Indications for Use *(Describe)*
The Vitality® Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vitality® Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Vitality® System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vitality® System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The use of the Vitality Spinal Fixation System in skeletally mature patients may include the fixation of the Instinct® JavaTM Spinal Fixation System hooks, Apex Spinal System hooks, or fixation of the Universal Clamp® Spinal Fixation System to the rods of the Vitality Spinal Fixation System. The Vitality Spinal Fixation System may also be used in skeletally immature patients when connected with the Universal Clamp® Spinal Fixation System.

In order to achieve additional levels of fixation in skeletally mature patients, the Vitality Spinal Fixation System may be connected to the Virage® OCT Spinal Fixation System and the Instinct® JavaTM Spinal Fixation System offered by Zimmer Spine, using rod connectors.

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.

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zimmer spine	**510(k) SUMMARY** ***Vitality*® Spinal Fixation System**

Date of Summary Preparation:	July 31, 2015
Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439 USA
Establishment Registration #:	2184052 (Minneapolis)
Company Contact (Primary):	Jonathan Gilbert Email: jonathan.gilbert@zimmer.com Office: 952.830.6385 Mobile: 612.419.4961
Common Name(s):	Pedicle Screw Spinal System
Device/ Trade Names(s):	*Vitality*® Spinal Fixation System
Device Classification:	Class III, Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease, and Spondylolisthesis Spinal Fixation. and Class II, Orthosis, Spinal Pedicle Fixation, Instabilities or Deformities; Adolescent Idiopathic Scoliosis and Spinal Interlaminal Fixation Orthosis
Regulation Number and Product Code(s):	21 CFR § 888.3070 / NKB, MNH, MNI, OSH, KWP, KWQ *Pedicle Screw Spinal System*

General Device Description:

The *Vitality* Spinal Fixation System is a thoracolumbar and sacroiliac fixation system designed to aid in the surgical correction of several types of spinal conditions. The system consists of a variety of spinal rods, pedicle screws, and connectors intended only to provide temporary stabilization during the development of a solid fusion of the spine with bone graft. The system can be rigidly locked into a variety of configurations, with each construct being customized to the patient's anatomy. All implants are single use only and should not be reused under any circumstances. The implant system is intended to be removed after solid fusion has occurred.

The system also includes instrumentation for insertion, securing and removal of the implants. All implants are made from medical grade titanium alloy; select rods are also available in medical grade cobalt chromium alloy.

Indications for Use:

The *Vitality*® Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the *Vitality*® Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the *Vitality*® System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The *Vitality*® System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The use of the *Vitality* Spinal Fixation System in skeletally mature patients may include the fixation of the Instinct® Java™ Spinal Fixation System hooks, Apex Spinal System hooks, or fixation of the Universal Clamp® Spinal Fixation System to the rods of the *Vitality* Spinal Fixation System. The *Vitality* Spinal Fixation System may also be used in skeletally immature patients when connected with the Universal Clamp® Spinal Fixation System.

In order to achieve additional levels of fixation in skeletally mature patients, the *Vitality* Spinal Fixation System may be connected to the Virage® OCT Spinal Fixation System and the Instinct® Java™ Spinal Fixation System offered by Zimmer Spine, using rod connectors.

Summary of Technological Characteristics:

The technological characteristics for the Zimmer Spine *Vitality*® Spinal Fixation System, remain the same to the predicate devices listed above: same system's intended use, same mechanical and functional scientific technology; same materials and the same substantially equivalent performance characteristics.

Summary of Performance Testing:

Non-clinical testing of the implant components of the subject *Vitality* Spinal Fixation System were assessed and tested appropriately to design controls; i.e. ASTM Standards.

- Bench Testing was conducted per ASTM F1717 for Static Torsion, Static and Dynamic Compression Bending.
- Bench Testing was conducted per ASTM F1798 for (axial, torsional) grip strength.

Conclusions

Zimmer Spine considers the subject *Vitality*® Spinal Fixation System to be substantially equivalent to the primary predicate device for this submission, the Biomet Spine Polaris Spinal System, K133746, SE date 3/12/14 as it is similar with respect to technical characteristics, design and intended use. The subject device is also equivalent to additionally cleared Zimmer Spine spinal systems: Sequoia - K131980, Virage - K133556, Title 2 - K133086 and Instinct Java – K123552 with respect to the implants used to assess performance. These additional clearances are noted for reference purposes only and not as a primary predicate devices for this application