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

June 24, 2015

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

Re: K151031
Trade/Device Name: Virage OCT Spinal Fixation System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: May 5, 2015
Received: May 6, 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,

Mark N. Melkerson -S

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 below.

510(k) Number *(if known)*
K151031

Device Name
Virage OCT Spinal Fixation System

Indications for Use *(Describe)*
The Virage OCT Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine from T1-T3; traumatic spinal fractures and/or traumatic dislocations; instability of deformity; failed previous fusions (e.g., pseudoarthorsis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Virage OCT Spinal Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, The Virage OCT Spinal Fixation System may be connected to the Instinct Java and Sequoia Spinal Systems offered by Zimmer Spine, using rod connectors and transition rods. Refer to the Instinct Java and Sequoia Spinal System package insert for a list of the system specific indications of use.

The titanium SONGER® Spinal Cable System to be used with the Virage OCT Spinal Fixation System allows for cable attachment to the posterior cervical or thoracic spine.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Date of Summary Preparation:	June 16, 2015
Company:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439 USA
Establishment Registration Number:	2184052 (Minneapolis)
Company Contact:	Jon Gilbert Email: jonathan.gilbert@zimmer.com Office: 952.830.6385 Email Fax: 952.837.6985
Device/Trade Name:	*Virage*® OCT Spinal Fixation System
Common Name:	Posterior, Cervical Pedicle Screw Spine Fixation Spinal Interlaminar Fixation Orthosis Posterior Cervical System
Regulatory Identification/ Classification:	Orthosis, Cervical Pedicle Screw Spinal Fixation Orthopaedic and Rehabilitation Devices Panel Product Code: NKG Unclassified, Pre-Amendment Spinal Interlaminar Fixation Orthosis Regulation Number: 888.3050 Product Code: KWP Class II

General Device Description:

The Zimmer Spine *Virage*® OCT Spinal Fixation System is a posterior system intended for the Occipital-Cervical-Thoracic spine (Occiput-T3). The system consists of a variety of rods, anchors, screws and connectors to build a spinal construct as necessary for the individual patient. The system also includes the instruments necessary for inserting and securing the implants. The implants are intended to be removed after solid fusion has occurred.

The *Virage* System implants are fabricated from medical grade titanium alloy or medical grade cobalt chromium alloy. Implants made from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same construct. All implants are single use only and should not be reused under any circumstances.

Indications for Use:

The Virage OCT Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine from T1-T3; traumatic spinal fractures and/or traumatic dislocations; instability of deformity; failed previous fusions (e.g., pseudoarthorsis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Virage OCT Spinal Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, The Virage OCT Spinal Fixation System may be connected to the Instinct Java and Sequoia Spinal Systems offered by Zimmer Spine, using rod connectors and transition rods. Refer to the Instinct Java and Sequoia Spinal System package insert for a list of the system specific indications of use.

The titanium SONGER® Spinal Cable System to be used with the Virage OCT Spinal Fixation System allows for cable attachment to the posterior cervical or thoracic spine.

Summary of Technological Characteristics:

The technological characteristics for the Zimmer Spine *Virage OCT Spinal Fixation System*, remain the same as 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.

Performance mechanical testing concluded the *Virage* open rod connector performed as intended and fundamental scientific technology remains unchanged from the predicate device. The *Virage* open rod connector is substantially equivalent to the predicate *Virage* System connectors. The technological characteristics including the basic design and materials, i.e. medical grade titanium alloy, are the same.

Summary of Performance Testing:

Published literature and the following non-clinical testing of the Virage open rod connector of the subject Virage OCT Spinal Fixation System demonstrate substantial equivalence:

- Testing conducted per ASTM F1798 for Axial and Torsional Gripping
- Testing was conducted per ASTM F1717 for Static Torsion, Static and Dynamic Compression Bending.

In addition, sterilization and biocompatibility were assessed and determined that the subject and predicate device systems & components are substantially equivalent for sterilization and biocompatibility.

Substantial Equivalence:

Zimmer Spine considers the subject *Virage* OCT Spinal Fixation System to be substantially equivalent to the currently commercialized predicate device listed above because it is similar with respect to technical characteristics, performance, design and intended use.

Identification of Legally Marketed Devices:

The subject *Virage* OCT Spinal Fixation System is substantially equivalent to the predicate cervical spinal system – the VERTEX® Reconstruction System (primary predicate) cleared by the FDA (K143471 - SE 02/06/15). The subject device is also equivalent to the previously cleared Virage OCT Spinal Fixation System most recently cleared by the agency (K133556 - SE 06/02/14) with respect to the implants used to create the constructs utilized for the indications sought. The earlier Virage OCT Spinal Fixation System clearance is noted for reference purposes only and not as a primary predicate device for this application.