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

February 16, 2016

Zimmer Spine, Incorporated
Mr. Ted Kuhn
Regulatory Affairs Project Manager
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K153631
Trade/Device Name: Zimmer Virage® OCT Spinal Fixation System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: January 27, 2016
Received: January 28, 2016

Dear Mr. Kuhn:

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 Parts 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)*

K153631

Device Name
Zimmer Virage® OCT Spinal Fixation System

Indications for Use *(Describe)*

The Zimmer Virage® OCT Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct into 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 Zimmer 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 Zimmer 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 Zimmer 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."

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Date of Summary Preparation:	December 17, 2015
Company:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439 USA
Establishment Registration Number:	2184052 (Minneapolis)
Company Contact:	Ted Kuhn Regulatory Affairs Product Manager Email: Ted.Kuhn@zimmerbiomet.com Phone: 303-501-8549 Fax: 303-501-8444
Device/Trade Name:	Zimmer Virage® OCT Spinal Fixation System
Common Name:	Posterior, Cervical Pedicle Screw Spinal Fixation Spinal Interlaminar Fixation Orthosis Posterior Cervical System
Regulatory Identification/Classification:	Orthosis, Cervical Pedicle Screw Spinal Fixation Orthopedic and Rehabilitation Devices Panel Product Code: NKG Unclassified, Pre-Amendment Spinal Interlaminar Fixation Orthosis Regulation Number: 888.3050 Product Code: KWP Class II
Primary Predicate Device:	Virage OCT Spinal Fixation System, K151031
Reference Devices:	Virage OCT Spinal Fixation System (K133556); Zimmer Minit Posterior Cervical and Upper Thoracic Fixation System (K070282); NuVasive OCT System (K071435)

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.

The modification is to increase the torque limit used with the Virage® OCT Spinal Fixation System.

Indications for Use:
The Zimmer Spine Virage® OCT Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct into 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 Zimmer Spine 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 Zimmer Spine Virage® OCT Spinal Fixation System allows for cable attachment to the posterior cervical or thoracic spine.

Summary of Technologies:
The technological characteristics for the Zimmer Spine Virage® OCT Spinal Fixation System remain the same as the predicate device in regards to intended use, mechanical performance, functional scientific technology and materials.

Performance Data:
Performance mechanical testing was conducted to confirm that the Zimmer Spine Virage® OCT Spinal Fixation System performs as intended and that the fundamental scientific technology remains unchanged from the predicate and referenced devices. The Zimmer Spine Virage® OCT Spinal Fixation System is substantially equivalent and demonstrates that the device performs as well as or better than the primary predicate and thus can be found substantially equivalent to the predicate system. The non-clinical tests performed were based on ASTM F2706 and ASTM F1717.

Substantial Equivalence:
The modified Zimmer Spine Virage® OCT Spinal Fixation System has the same intended use, operating principles, basic design, materials, packaging, and shelf life as the predicate system. The intended use of the Zimmer Spine Virage® OCT Spinal Fixation System, as described in its labeling, has not changed. Furthermore, the modification to the Zimmer Spine Virage® OCT Spinal Fixation

System does not raise new issues of safety or effectiveness, as supported by the risk analysis, verification, and validation activities. Thus, the Zimmer Spine Virage® OCT Spinal Fixation System described in this submission is substantially equivalent to the predicate device.