

JUN 02 2014

	<b>510(k) SUMMARY</b> <b>Virage OCT Spinal Fixation System</b>
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**Date of Summary Preparation:** May 8, 2014

**Company:** Zimmer Spine, Inc.  
7375 Bush Lake Road  
Minneapolis, MN 55439  
USA

**Establishment Registration Number:** 2184052 (Minneapolis)

**Company Contact:** Holly Seppanen  
Regulatory Affairs Project Manager  
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**Trade Name(s):** Virage OCT Spinal Fixation System

**Device Name (Common Name):** Spinal Fixation System

**Device Classification:** Class II

**Regulation Number and Product Code(s):** 21 CFR § 888.3050 / KWP

**Regulation Name:** Appliance, Fixation, Spinal Interlaminar

**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, transverse connectors, screws, and polyaxial screws to achieve an implant construct as necessary for the individual case. The system also includes the instruments necessary for inserting and securing the implants. The implant system is intended to be removed after solid fusion has occurred.

The Virage System implants are fabricated from medical grade titanium alloy and 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. Refer to the product label to determine if instrumentation is intended for single use.

**Indications for Use:**

When intended to promote fusion of the occipitocervical spine, cervical spine and the thoracic spine, (Occiput -T3), the **Virage** OCT Spinal Fixation System is indicated for the following:

Degenerative disc disease (DDD) (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

**Occipitocervical Plate/Rod/Occipital Screws/Hooks**

Occipitocervical plate, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat occipitocervical and cervical conditions, the occipital screws are limited to occipital fixation only. The occipital screws are not intended for the cervical spine.

**Hooks and Rods**

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

**Thoracic Screws**

The use of thoracic screws is limited to placement in T1-T3 *for anchoring the construct only*. The thoracic screws are not intended to be placed in the cervical spine.

**Rod Connectors**

The **Virage** OCT Spinal Fixation System can also be linked to the Instinct Java and Sequoia Spinal Systems offered by Zimmer Spine using rod connectors and transition rods.

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 *Virage System* is a posterior system intended for the Occipital-Cervical-Thoracic spine (Occiput-T3). The system consists of a variety of rods, anchors, transverse connectors, screws, and polyaxial screws to achieve a spinal implant construct as necessary for the individual case. The *Virage System* also includes the instruments necessary for inserting and securing the implants.

All implants are single use only and are not to be reused under any circumstances. All instruments are reusable. All implants and instruments are provided clean and non-sterile and must be sterilized by the end user prior to use.

The medical grade titanium alloy utilized in the *Virage System* implants is Ti-6Al-4V ELI per ASTM F136. The medical grade cobalt chromium alloy utilized in the *Virage System* implants is Co-28Cr-6Mo per ASTM F1537.

Performance mechanical testing concluded the Virage System performed as intended and fundamental scientific technology remains unchanged from the predicate devices. The Virage System is substantially equivalent to the predicate devices. The technological characteristics including the basic design and materials, i.e. medical grade metallic constructs, are the same.

In summary, the subject *Virage System* utilizes medical grade metallic constructs and does not change the fundamental scientific technology of the device as compared to the predicates, it will continue to operate in the same way.

**Summary of Performance Testing:**

Worst case constructs of the occipito-cervical portion of the *Virage System* were tested per ASTM F2706. Worst case constructs of the thoracic portion of the *Virage System* were tested per ASTM F1717. Select components were also tested per ASTM F1798. All performance testing passed the acceptance criteria and demonstrated the device performed as well or better than the predicate systems.

**Identification of Legally Marketed Devices:**

Predicate Device Name	FDA 510k Number
Endius Minit Posterior Cervical and Upper Thoracic Fixation System	K070282
NuVasive® OCT System	K071435
Synthes Synapse, Cervifix, Cervifix Starlock	K091689, K991089, K994187
Vertex Reconstructive System	K003780, K123656

**Substantial Equivalence:**

Zimmer Spine considers the subject *Virage OCT Spinal Fixation System* product performance to be substantially equivalent to the predicate devices because there is no significant difference in intended use, mechanical and functional performance and fundamental scientific technology. No new issues of safety and effectiveness are raised due to the similarities between the subject and the legally marketed predicate devices, as each are used to treat similar clinical conditions and represent a similar basic design concept.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

June 2, 2014

Zimmer Spine, Incorporated  
Ms. Holly Seppanen  
Regulatory Affairs Project Manager  
7375 Bush Lake Road  
Minneapolis, Minnesota 55439

Re: K133556

Trade/Device Name: *Virage* OCT Spinal Fixation System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: Class II  
Product Code: KWP  
Dated: May 8, 2014  
Received: May 9, 2014

Dear Ms. Seppanen:

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.

Page 2 – Ms. Holly Seppanen

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,

**Ronald P. Jean -S** for

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)  
K133556

Device Name  
Virage OCT Spinal Fixation System

Indications for Use (Describe)

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 807 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)

Zane W. Wyatt

Division of Orthopedic Devices

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Office of Chief Information Officer  
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*PRAStaff@fda.hhs.gov*

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