April 4, 2025

Highridge Medical, LLC
Regan Ream
Regulatory Affairs Senior Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K250332
Trade/Device Name: Virage® OCT Spinal Fixation System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior cervical screw system
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: February 4, 2025
Received: February 5, 2025

Dear Regan Ream:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250332

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 Vital Spinal Fixation System offered by Highridge Medical, using rod connectors and transition rods. Refer to the Vital Spinal Fixation System package insert for a list of the system specific indications of use. The Vital/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).

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.

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4/4/2025

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.

Sponsor Information	
Name	Highridge Medical, LLC (Zimmer Biomet Spine, Inc.)
Address	10225 Westmoor Dr. Westminster, CO 80021
Establishment Registration	3012447612
Contact Person(s)	Regan Ream Regulatory Affairs Senior Specialist Phone : (720) 227.2187 Email : Regan.Ream@highridgemedical.com
	Anjanet Mort Regulatory Affairs Manager Phone : (720) 839.7926 Email : Anjanet.Mort2@highridgemedical.com

Device Information	
Proprietary Name	Virage® OCT Spinal Fixation System
Common Name	Posterior Cervical Screw System
Device Class	Class II
Device Panel	Orthopedic Panel (87)
Regulation Number	21 CFR § 888.3075 21 CFR § 888.3050
Classification Name-Product Code(s)	Posterior Cervical Screw System (NKG) Appliance, Fixation, Spinal Interlaminal (KWP)
Predicate Devices	Primary Predicate: *Virage® System (K153631)*

Device Description

The Virage® OCT Spinal Fixation System is a posterior fixation system intended to provide immobilization and stabilization of the Occipital-Cervical-Thoracic spine (Occiput-T3). The system consists of a variety of rods, anchors, 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.

Intended Use / 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.

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Substantial Equivalence Assessment

The technological characteristics of the subject Virage® System components remain the same as, or similar to, the predicate Virage® System (K153631) in regard to intended use, indications for use, design, manufacturing methods, fundamental technology, and operational principles. The purpose of this submission is to seek clearance of additional rod-to-rod connectors for use with the Virage® System and the MRI conditional information provided and references to the Reusable Lifespan Manual in the Instructions for Use for the Virage® System. Additionally, this submission discloses various minor changes to the previously cleared Virage® System that were introduced via Letters-to-File.

Specifically, the subject Virage® System is manufactured using the same materials and processes used to manufacture the previously cleared Virage® System. Additionally, the subject devices have the same intended use as the predicate devices. As such, the performance assessments of the subject devices are substantially equivalent to the predicate devices. Furthermore, the subject Virage® System has the same methods and technological characteristics as its cleared predicate Virage® System (K153631).

MRI Compatibility

Previously, labeling for the Virage® System indicated that the system had not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The following MR environment testing was evaluated:

- ***ASTM F2052****: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- ***ASTM F2182****: Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging*
- ***ASTM F2213****: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*
- ***ASTM F2119:*** *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*

Based on testing of the Virage® System in a magnetic resonance environment, the labeling was updated to include the addition of “MR Conditional information”. For additional information, See **Electromagnetic Compatibility** and **Labeling**.

Reusable Lifespan Manual

The Reusable Lifespan Manual (See **Labeling)** is intended to assist the user in determining whether a reusable instrument is no longer suitable for use. This manual provides supplemental information to the Virage® System IFU; however, is not specific to the Virage® System. This manual is included in this submission as a reference only, as the Virage System Instructions For Use were updated to include references to the Reusable Lifespan Manual. Upon clearance of this 510k, physicians can access the Reusable Lifespan Manual via the Highridge Medical labeling website (ifu.highridgemedical.com).

Performance Testing Conclusion

Mechanical testing and usability were evaluated, which all met the acceptance criteria for the worst-case subject connectors. Additionally, packaging, cleaning and sterilization were evaluated to determine no risks were introduced to the system.

Static torsion and dynamic/static compression bending was performed in accordance with *ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Mode (Recognition Number: 11-388).* Axial/Torsional grip testing was performed in accordance with *ASTM F1798 Standard Test Methods for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants (Recognition Number: 11-402).*

A risk assessment was conducted that found risks have been reduced as far as possible and neither alternative design nor therapeutic options exist to avoid the introduced risks without introducing equally severe and/or probable risks.

Substantial Equivalence Conclusion

The Virage® System's indications for use, intended use, design, materials, and performance assessments are substantially equivalent to the currently marketed Virage® System. As such, Highridge Medical, LLC concludes that the subject Virage® System is substantially equivalent to the predicate Virage® System.