August 27, 2021

Zimmer Biomet Spine, Inc.
David Pollard
Regulatory Affairs Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K212023
Trade/Device Name: Virage Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 28, 2021
Received: June 29, 2021

Dear David Pollard:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Jesse Muir -S

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212023

Device Name
Virage® Navigation System

Indications for Use *(Describe)*
The Virage® Navigation System Instruments are to be used during the preparation and placement of Virage® OCT polyaxial screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in open procedures. The Virage® Navigation System Instruments are specifically designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

The Virage® Navigation Instruments are also compatible with the Zimmer Biomet Universal Power System and the WalterLorenz® Surgical Assist Arm.

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.

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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.

510(k) Number	K212023
Preparation Date	June 28, 2021
Applicant/Sponsor	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	David Pollard Regulatory Affairs Specialist Phone: 303-253-0056 Fax: 303-501-8444
Trade Name	Virage NavigationSystem
Common Name	Stereotaxic Instrument
Device Class	Class II
Classification Name	OLO – Orthopedic Stereotaxic Instrument (21 CFR882.4560)
Device Panel	Orthopedic
Predicate Devices	*Primary Predicate*: Navigated INFINITY™ Instruments (K173338) *Additional Predicate*: StealthStation® System (K170011) *Reference Devices:* Virage OCT Spinal Fixation System (K153631) WalterLorenz Surgical Assist Arm (K190576) Zimmer Universal Power System (N/A)

Device Description & Technological Characteristics

The Virage Navigation System is comprised of non-sterile, reusable instruments including drills, taps, and drivers that can be operated manually and/or under a power surgical technique to prepare for and insert Virage OCT polyaxial screws. These instruments are intended to be used with the Medtronic StealthStation® System to assist surgeons in precisely locating anatomical structures. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems allows the surgeon access to real-time, multi-plane 3D images (and 2D images) thereby providing confirmation of hardware placement.

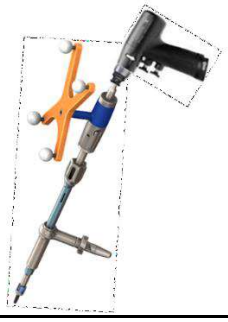
Intended Use / Indications for Use

The Virage® Navigation System Instruments are tobe used during the preparationand placement of Virage® OCT polyaxial screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in open procedures. The Virage® Navigation Instruments are specifically designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

The Virage® Navigation Instruments are also compatible with the Zimmer Biomet Universal Power System and the WalterLorenz® Surgical Assist Arm.

Comparison of Technological Characteristics to Primary Predicate

Thepurpose of this submissionis to seekclearance for therelease ofstereotactic instruments for the implantation of Virage polyaxial screws while utilizing the existing Medtronic StealthStationsystem. The technological characteristics of the subject Virage Navigation System components remain the same as, or similar to, the predicate Navigated Infinity Instruments (K173338) in regard to intended use, indications for use, design, fundamental technology, and operational principles. **Table 7-1** provides a more detailed comparisonbetween the subject devices and the primary predicate.

Specification	**Zimmer Biomet Spine, Inc.** ***Virage Navigation System*** *Subject Device*	**Medtronic** ***Navigated INFINITY Instruments*** *Primary Predicate Device*
510(k)	K212023	K173338
Device Name	*Virage Navigation System*	*Navigable Pedicle Preparation Instruments*
Image of System Construct		Not Available
Product Codes	OLO	OLO
Product Classification	▪ Orthopedic Stereotaxic Instrument	▪ Orthopedic Stereotaxic Instrument
Class	Class II	Class II
Instruments subject of submission	Instruments for navigation	Instruments for navigation
Navigatable Instruments	Preparation and placement instruments for screws	Preparation and placement instruments for screws
Indicatons For Use	The Virage® Navigation System Instruments are to be used during the preparation and placement of Virage® OCT polyaxial screws during spinal surgery to	Medtronic Navigated Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist

	assist the surgeon in precisely locating anatomical structures in open procedures. The Virage® Navigation Instruments are specifically designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy. The Virage® Navigation Instruments are also compatible with the Zimmer Biomet Universal Power System and the WalterLorenz® Surgical Assist Arm.	the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Instruments are specifically designed for use with the StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Instruments are also compatible with the IPC™ POWEREASE™ System.

The Virage Navigation System is substantially equivalent to the predicate system as a spinal fixation device regarding intended use, indications for use, and fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. Accuracy testing and other supporting testing sufficiently demonstrate the substantial equivalence of the subject instruments to the Navigated Infinity Instruments, which has been cleared for stereotactic guidance using the StealthStation during orthopedic surgery procedures. Furthermore, validation testing also proved the subject instruments to be compatible and safe for use with StealthStation and the additional predicate systems. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates.

Summary of Performance Data

To support substantial equivalence, accuracy testing of the stereotactic instruments of the subject Virage Navigation System were assessed and tested appropriately in accordance with ASTM standards. The assessment concluded that the use of the proposed stereotactic instruments for the implantation of Virage screws is safe and effective for use. Performance testing included tests per ASTM F2554-18, *Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems*, and the worst-case instruments met the acceptance criteria according to ASTM F2554-18. In all instances, the proposed instrument system functioned as intended and demonstrated substantial equivalence to the predicate device(s).

To further support substantial equivalence, a clinical validation lab of the navigated and powered instruments of the subject Virage Navigation System was conducted, and the results were compared against literature. The assessment concluded that the subject instruments use for powered pedicle screw insertion and fixation is safe and effective for use. This validation provided further evidence that the subject instruments are compatible with StealthStation, WalterLorenz Surgical Assist Arm and Zimmer Biomet Universal Power System.

Conclusion

The subject Virage Navigation System has been shown through comparison, accuracy testing, additional verification testing and a clinical validation to be substantially equivalent to the identified predicate device(s). Based on this information the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates.