



April 5, 2024

ZimVie Spine (Zimmer Biomet Spine, Inc.)
Anjanet Mort
Regulatory Affairs Manager
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K240647
Trade/Device Name: Virage® Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 6, 2024
Received: March 7, 2024

Dear Anjanet Mort:

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.

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,

Shumaya Ali -S

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

Indications for Use

Submission Number (if known)

K240647

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. When used with the Medtronic NavLock arrays, the Virage Navigation instruments can be used with the Medtronic StealthStation® S7. When used with the ZimVie reference arrays, the Virage Navigation instruments can be used with the Brainlab Navigation System.

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.

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3/6/2024

510(k) Summary

Sponsor Information	
Name	Zimmer Biomet Spine, Inc. (d/b/a ZimVie Spine)
Address	10225 Westmoor Dr. Westminster, CO 80021
Establishment Registration	3012447612
Primary Contact Person(s)	Regan Ream Regulatory Affairs Associate Phone : (720) 227-2187 Email : Regan.Ream@zimvie.com
	Anjanet Mort Regulatory Affairs Manager Phone: (720) 839-7926 Email: Anjanet.Mort2@zimvie.com

Device Information	
Proprietary Name	Virage® Navigation System
Common Name	Stereotaxic Instruments
Device Class	Class II
Device Panel	Orthopedic Panel (87)
Regulation Number	21 CFR § 882.4560
Classification Name-Product Code(s)	Orthopedic Stereotaxic Instrument (OLO)
Predicate Devices	Primary Predicate: <i>Virage® Navigation System (K212023)</i>
Reference Devices	Reference Device #1 <i>Medtronic StealthStation S7 (K133444)</i>
	Reference Device #2 <i>Brainlab Navigation System (K212245)</i>

Device Description

The Virage® Navigation System is comprised of nonsterile, 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. The Virage Navigation System instruments are designed for use with either the Medtronic StealthStation S7 or the Brainlab Spine & Trauma Navigation software (version 2.0 and higher). The ZimVie reference arrays can only be used with the Brainlab Spine & Trauma Navigation System. The Virage Navigation System is also compatible with the Zimmer Biomet Universal Power System.

Intended Use / Indications 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 assist the surgeon in precisely locating anatomical structures in open procedures. When used with the Medtronic NavLock arrays, the Virage Navigation instruments can be used with the Medtronic StealthStation® S7. When used with the ZimVie reference arrays, the Virage Navigation instruments can be used with the Brainlab Navigation System.

Substantial Equivalence Assessment

The technological characteristics (the intended use, scientific technology and design, performance assessment, and operational principles) of the subject Virage® Navigation System components remain the same as, or similar to, the predicate Virage® Navigation System (K212023) or the reference Brainlab Navigation Systems (K212245).

The only modification to the indications for use was to add the option of using the Brainlab Navigation System with the Virage® Navigation System instruments through the introduction of the newly developed reference arrays. The subject of the submission introduced new arrays to support the Brainlab Navigation System, introducing a new material (7075-T6 aluminum), but the device remains biocompatible and within the risk profile of the Virage® Navigation System. The subject of the submission also details the adoption of automated cleaning instructions, but the automated cleaning instructions do not introduce any new risks to the Virage® Navigation System.

Performance Testing Conclusion

The following verification and validation activities were performed: positional accuracy, usability, and tolerance analysis, which all met the acceptance criteria when the Virage Navigation instruments were attached to the ZimVie reference arrays. Additionally, packaging and sterilization were evaluated to determine no risks were introduced to the system. Automated cleaning instructions were reviewed and adopted by the Virage Navigation System, but no risks were introduced to the system. The new reference arrays are non-patient contacting and are composed of stainless-steel (array body) and aluminum (array holder), and both materials were evaluated per ISO 10993-1. Since the device and device materials have neither direct nor indirect contact with the body, additional biocompatibility information is not necessary.

A risk assessment was conducted that found risks have been reduced as far as possible and concluded that the benefits associated with spine surgery and the use of the option of using the Brainlab Navigation System with the Virage® Navigation System outweigh the risks related to polyaxial screw placement.