November 16, 2023

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

Re: K233443
Trade/Device Name: Vital™ Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 18, 2023
Received: October 19, 2023

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

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)*
K233443

Device Name
Vital™ Navigation System

Indications for Use *(Describe)*
The Vital Navigation System instruments are used during the preparation and placement of the Vital and Vitality System screws during spinal surgery to precisely locate anatomical structures in either open or minimally invasive procedures. The Vital Navigation System instruments are designed for use with either the Medtronic StealthStation S7 or the Brainlab Spine & Trauma Navigation software. The ZimVie reference arrays can only be used with the Brainlab Spine & Trauma 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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11/16/2023

K233443 - 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)	Anjanet Mort Regulatory Affairs Manager Phone : (720) 839-7926 Email : Anjanet.Mort2@zimvie.com
	Regan Long Regulatory Affairs Associate Phone: (720) 227.2187 Email: Regan.Long@zimvie.com

Device Information		
Proprietary Name	Vital™ 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:	*Vital™ Navigation System (K191722)*
Reference Devices	Reference Device #1	*Medtronic StealthStattion S7 (K133444)*
	Reference Device #2	*Brainlab Navigation System (K212245)*

Device Description

The Vital™ Navigation System is comprised of nonsterile, reusable instruments including awls, probes, taps, and drivers that can be operated manually. The Vital Navigation System instruments are designed for use with either the Medtronic StealthStation S7 or the Brainlab Spine & Trauma Navigation software. The ZimVie reference arrays can only be used with the Brainlab Spine & Trauma Navigation System. Both combinations are used to assist surgeons in precisely locating anatomical structures in either open or minimally invasive procedures for preparation and placement of Vital and Vitality Screws. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the

accuracy of advanced surgical procedures. The use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.

As with all orthopedic surgical procedures, detailed preoperative planning is essential. Preoperative diagnostic evaluation, followed by carefully executed surgical technique is required. Postoperative care, individualized to suit the particular injury/disease requirements, is essential for optimum outcome. The surgeon must be fully aware of the risks and complications inherent to this type of surgery. Only those individuals with specialized training and experience in spinal surgery should attempt use of the instruments.

The instrument cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays and holders. The instrument cases are perforated to allow steam to penetrate these various materials and components. The instrument cases will allow for sterilization of the contents to occur in a steam sterilizer utilizing a cycle that has been validated by the user for the equipment and procedures employed at the user facility. Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap or rigid container to maintain sterility.

Intended Use / Indications for Use

The Vital Navigation System instruments are used during the preparation and placement of the Vital and Vitality System screws during spinal surgery to precisely locate anatomical structures in either open or minimally invasive procedures. The Vital Navigation System instruments are designed for use with either the Medtronic StealthStation S7 or the Brainlab Spine & Trauma Navigation software. The ZimVie reference arrays can only be used with the Brainlab Spine & Trauma Navigation System.

Substantial Equivalence Assessment

The technological characteristics (the intended use, scientific technology and design, performance assessment, and operational principles) of the subject Vital™ Navigation System components remain the same as, or similar to, the predicate Vital™ Navigation System (K191722) 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 Vital™ Navigation System instruments through the introduction of the newly developed reference arrays. The subject of the submission introduced 4 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 Vital™ 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 Vital Navigation instruments were attached to the ZimVie reference arrays. Additionally, packaging, sterilization and cleaning instructions were evaluated to determine 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 Vital™ Navigation System outweigh the risks related to posterior pedicle screw placement.