January 7, 2022

ZimVie (Zimmer Biomet Spine, Inc.)
Hanna Aucoin
Regulatory Affairs Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K213720
Trade/Device Name: Vital Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 20, 2021
Received: November 24, 2021

Dear Hanna Aucoin:

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,

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)*
K213720

Device Name
Vital Navigation System

Indications for Use *(Describe)*
Vital Navigation instruments are to be used during the preparation and placement of Vital and Vitality screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Vital 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.

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.

Preparation Date	January 7, 2022
Applicant / Sponsor	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	Hanna Aucoin Regulatory Affairs Specialist Phone: 303-533-1075 Fax: 303-501-8444
Alternate Contact	Alex Pawlowski Regulatory Affairs Associate Director Phone: 303-533-1062 Fax: 303-501-8444
Trade Name	Vital Navigation System
Common Name	Stereotaxic Instrument
Device Class	Class II
Classification Name	OLO – Orthopedic Stereotaxic Instrument (21 CFR 882.4560)
Device Panel	Orthopedic
Predicate Devices	Primary Predicate: *Vital Navigation System* (K191722) Additional Predicates: *Vital Spinal Fixation System* (K203507) *Medtronic StealthStation System* (K133444) *VIPER PRIME Navigated Inserter* (K170937)

Device Description

The Vital Navigation System is comprised of nonsterile, reusable instruments including awls, probes, taps, and drivers that can be operated manually. These instruments are intended to be used with the Medtronic Synergy™ Experience StealthStation® System 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. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.

Through the introduction of new styluses in this submission, the previously cleared Vital Navigation Taps and Reduction Driver (K191722) can be used with the existing Vital MIS PAT Handle (K203507) to allow the user to navigate while using the PAT or PASIT assembly. It is important to note that these styluses will not be navigated. As such, the toolcard for the NavLock taps or NavLock driver will not change with this new use scenario.

Intended Use / Indications for Use

Vital Navigation System Instruments are to be used during the preparation and placement of Vital and Vitality screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Vital 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.

Substantial Equivalence Summary

The technological characteristics of the subject Vital® Navigation System components remain the same as, or similar to, the predicate Vital® Navigation System (K191722) in regards to intended use, indications for use, design, manufacturing methods, fundamental technology, and operational principles. The purpose of this submission is to seek clearance on an additional technique for the implantation of Vital® screws using the existing Vital® Navigation instruments.

Specifically, the subject Vital Navigation styluses are manufactured using the same materials and processes used to manufacture the previously cleared Vital MIS PAT/PASIT styluses. Furthermore, the subject styluses have the same intended use as the predicate styluses: a cortex-breaking stylus to dock the assembly to the bone. As such, the performance characteristics of the subject styluses are substantially equivalent to the predicate styluses. Additionally, the subject Vital Navigated PAT and Vital Navigated PASIT techniques share similar methods and technological characteristics as its cleared predicates (Vital MIS – K203507 and VIPER PRIME Navigated Inserter – K170937). The subject and predicate techniques all apply existing navigation instrumentation to a guidewire-less method for tapping and direct-to-screw insertion during pedicle screw placement.

Risk Evaluation Summary

A risk assessment was conducted to review the additional technique introduced in this submission. This risk assessment resulted in the inclusion of additional warnings in the labeling. The previous labeling verification used to evaluate risk control measures for the predicate Vital® Navigation System (K191722) remains acceptable as the methods used are unchanged by the introduction of the new styluses and navigated PAT/PASIT techniques presented in this submission. Per *The Special 510(k) Program* issued by the FDA on September 13, 2019, a Special 510(k) is appropriate for this submission as the proposed change is being submitted by the legal manufacturer and a risk analysis format supports substantial equivalence.

Substantial Equivalence Conclusion

The Vital Navigation System is substantially equivalent to the predicate system as a spinal fixation device in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. Furthermore, accuracy testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components to the Navigated Instrument System which has been cleared for stereotactic guidance during orthopedic surgery procedures. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates.