



Zimmer Biomet Spine, Inc.
Alex Pawlowski
Regulatory Affairs Senior Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

October 24, 2019

Re: K190556
Trade/Device Name: Zimmer Biomet Universal Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 26, 2019
Received: July 29, 2019

Dear Alex Pawlowski:

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,

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

Indications for Use

510(k) Number (if known)

K190556

Device Name

Zimmer Biomet Universal Navigation System

Indications for Use (Describe)

The Zimmer Biomet Universal Navigation System is indicated for use during the preparation and insertion of Zimmer Biomet screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These adaptors 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 skull, a long bone or vertebra can be identified relative to an acquired image: CT or MR based model, fluoroscopy images, or digitized landmarks of 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K190556

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	July 26, 2019
Applicant/Sponsor	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	Alex Pawlowski Regulatory Affairs Senior Specialist Phone: 303-553-1062 Ted Kuhn Regulatory Affairs Associate Director Phone: 303-501-8549
Trade Name	Zimmer Biomet Universal Navigation System
Common Name	Stereotaxic Instrument
Device Class	Class II
Classification Name	OLO – Orthopedic Stereotaxic Instrument (21 CFR 882.4560)
Device Panel	Orthopedic
Primary Predicate	K122211 Synthes Navigable Pedicle Preparation Instruments
Secondary Predicate	K133444 Medtronic StealthStation
Reference Devices	K132884 Pathfinder NXT Spine System K151974 Polaris Spinal Fixation System K171907 Vitality Spinal Fixation System K172275 Vitality+ Power Instrument System, Vitality Spinal Fixation System

Device Description & Technological Characteristics:

The Zimmer Biomet Universal Navigation System includes Universal Adaptors that are intended to be used with instrumentation from Vitality Spinal Fixation System (including Vital Power Instrument System), Pathfinder NXT Minimally Invasive Pedicle Screw System, and Polaris Spinal Fixation System (including Cypher MIS Screw System) to facilitate preparation and insertion of Zimmer Biomet screws using navigation.

Intended Use / Indications for Use:

The Zimmer Biomet Universal Navigation System is indicated for use during the preparation and insertion of Zimmer Biomet screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The universal adaptors 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 pelvis or vertebra, can be identified relative to an acquired image: CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Summary of Technological Characteristics:

The technological characteristics of the subject Zimmer Biomet Universal Navigation System components remain the same as, or similar to, the predicates in regards to intended use, indications for use, design, manufacturing methods, materials, and operational principles. The purpose of this submission is to seek clearance to introduce new adaptors designed to interface with the already-Cleared surgical navigation system, Medtronic StealthStation System using the Medtronic SureTrak II instruments and already-Cleared pedicle screw preparation and insertion instruments to facilitate preparation and insertion of Zimmer Biomet screws using navigation.

Summary of Performance Data:

Validation activities are used to confirm the instruments meet performance requirements, providing assurance of device performance for their intended use, similar to predicate systems. Accuracy testing of the Zimmer Biomet Universal Navigation System Instruments was performed in accordance with ASTM F24554-18 *Standard Practice For Measurement of Positional Accuracy of Computer Assisted Surgical Systems*. Clinical data was not needed for the Zimmer Biomet Universal Navigation System.

Substantial Equivalence Conclusion:

The Zimmer Biomet Universal Navigation System is substantially equivalent to the predicate system in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, materials and operational principles. Furthermore, validation testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates.