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

October 29, 2019

Re: K192133
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: August 6, 2019
Received: August 7, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192133

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. The universal adaptors are specifically designed for use with the Zimmer Biomet ROSA One Spine System, which is indicated for providing spatial positioning and orientation of instrument holders or tool guides based upon an intraoperative plan developed with three dimensional imaging software provided that the required fiducial markers and rigid patient anatomy can be identified on 3D CT scans. The ROSA One Spine System is intended for the placement of pedicle screws in vertebrae with a posterior approach in the thoracolumbar region.

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	August 6, 2019
Applicant/Sponsor	Zimmer Biomet Spine, Inc. 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	Alex Pawlowski Regulatory Affairs Sr. Specialist Phone: 303-533-1062 Ted Kuhn Regulatory Affairs Associate Director Phone: 720-469-5055
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	K182848 ROSA One Spine Navigation System
Reference Devices	K133444 Medtronic StealthStation K132884 Pathfinder NXT Spine System K151974 Polaris Spinal Fixation System K183550 Vitality Spinal Fixation System, Vitality MIS

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 Vitality MIS), 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 Zimmer Biomet ROSA One Spine application, which is indicated for providing spatial positioning and orientation of instrument holders or tool guides based upon an intraoperative plan developed with three dimensional imaging software provided that the required fiducial markers and rigid patient anatomy can be identified on 3D CT scans. The ROSA One Spine application is intended to assist in the placement of pedicle screws in vertebrae with a posterior approach in the thoracolumbar region.

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, ROSA One Spine application, 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 ASTM F2554-18 *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.