July 12, 2023

Zavation Medical Products, LLC
Katie Motley
Design Engineer
3670 Flowood Drive
Flowood, Mississippi 39232

Re: K223808
Trade/Device Name: Zavation Navigation Instrument System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 9, 2023
Received: June 9, 2023

Dear Katie Motley:

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 -S

Shumaya Ali, MPH
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)*
K223808

Device Name
Zavation Navigated Instrument System

Indications for Use *(Describe)*
Zavation Navigated Instrument System are indicated for use during the placement of Zavation Spine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Zavation Navigated Instruments are reusable and are specifically designed for use with the Medtronic Navigation StealthStation System which are 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. Use of Zavation Navigated Instrument System is limited to use only with Zavation Spinal System and Zavation Z-Link$_{PC}$ System.

Please refer to the following Instructions for Use (IFU) and Surgical Techniques for complete system guides, descriptions, indications and warnings:

- Zavation Spinal System
- Zavation Z-Link$_{PC}$ System
- Medtronic StealthStation 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.

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
PRAStaff@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."

K223808
510K Summary

Date:	July 12, 2023
Submitter:	Zavation Medical Products, LLC 3670 Flowood Drive Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	Katie Motley
Type of 510(k) submission:	Traditional
Trade name:	Zavation Navigation Instrument System
Common name:	Orthopedic Sterotaxic Instrumentation
Classification regulation:	21 CFR 882.4560 Stereotaxic Instrument
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	OLO
Basis for submission	New Submittal

Device Description:
The Zavation Navigation instruments non-sterile, reusable instruments that can be operated manually. These instruments are intended to be used with the Medtronic StealthStation® System to aid in implantation of associated Zavation screw implants. The instruments are manufactured from stainless steel per ASTM F899

Indications for Use:
Zavation Navigated Instrument System are indicated for use during the placement of Zavation Spine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Zavation Navigated Instruments are reusable and are specifically designed for use with the Medtronic Navigation StealthStation System which are 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. Use of Zavation Navigated Instrument System is limited to use only with Zavation Spinal System and Zavation Z-Link$_{PC}$ System.

Please refer to the following Instructions for Use (IFU) and Surgical Techniques for complete system guides, descriptions, indications and warnings:

- Zavation Spinal System
- Zavation Z-Link Posterior Cervical System
- Medtronic StealthStation Navigation System

Materials:
This submission seeks clearance of just the Zavation Navigation Instrument System. Instruments are made from Stainless Steel according to F899. This is the same material used in the predicate devices.

List of Instruments:
Zavation Navigated Instrument System consists of taps, probes, and screwdrivers both canulated and non-canulated indicated to be used with Zavation Spinal System; Zavation Navigation System also includes taps, probes, & a screwdriver indicated to be used with Zavation Z-Link Posterior Cervical System.

Predicate Device:
Primary – K170679 MEDTRONIC NAVIGATED INSTRUMENTS FOR USE WITH STEALTHSTATION® AND IPC® POWEREASE SYSTEMS
Additional – K153603 Alphatec Navigation Instruments; Alphatec Spine, Inc.
Reference - K211113 Zavation Spinal System; Zavation Medical Products, LLC.
Reference – K211993 Zavation Z-Link$_{PC}$ System; Zavation Medical Products, LLC.

Technological Characteristics:
The Zavation Navigated Instrument System are non-sterile, reusable instruments that can be operated manually. These instruments are intended to be used with the Medtronic StealthStation® System to aid in implantation of associated Zavation screw implants. The instruments are manufactured from stainless steel per ASTM F899.

Performance Data:
The following testing was performed:
- Accuracy and Precision Testing of Navigation System per ASTM F2554-10 *Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical System*
- Mating Interface Assessments
- CMM Inspection
  Instrument Verification

Validation testing includes 1:1 accuracy and performance testing of the subject and predicate device in a simulated surgical navigation use environment.

Substantial Equivalence Conclusion:
The overall technological characteristics of the Zavation Navigated Instrument System, including working length, material, and intended use are very similar to the predicate systems. The nonclinical tests conducted also lead to the conclusion that the Zavation Navigated Instrument System is substantially equivalent to the predicate Medtronic navigation instruments when used with the StealthStation™ System and NavLock Tracker.