December 19, 2019

Spinal Elements Inc.
Julie Lamothe
Vice President Regulatory Affairs
3115 Melrose Dr. Suite 200
Carlsbad, California 92010

Re: K190881
Trade/Device Name: Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 18, 2019
Received: November 20, 2019

Dear Julie Lamothe:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190881

Device Name
Spinal Elements Navigated Instruments

Indications for Use *(Describe)*
Spinal Elements Navigated Instruments are intended to be used during the preparation and placement of Spinal Elements screws (Overwatch®, Savannah® and Mercury® Fixation Systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are 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 vertebra, can be identified relative to a 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.

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510(k) Summary
Navigated Instruments

510(k) Number: K190881

Manufacturer Identification

Submitted by: Spinal Elements, Inc.
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Carlsbad, CA 92010
760-607-0121

Contact Information: Julie Lamothe
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Date Prepared: December 16, 2019

Proprietary Device	Spinal Elements Navigated Instruments
Common Name	Stereotaxic Instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	21 CFR 882.4560
Regulatory Class	Class II
Product Code	OLO

Device Description

Spinal Elements Navigated instruments are non-sterile, reusable instruments designed to function with the Medtronic StealthStation® System. Spinal Elements Navigated instruments are for use with Spinal Elements pedicle screw systems, specifically, Overwatch®, Mercury® and Savannah® pedicle screw systems. Instruments are manufactured from stainless steel.

Indications for Use

Spinal Elements Navigated Instruments are intended to be used during the preparation and placement of Spinal Elements screws (Overwatch®, Savannah® and Mercury® Fixation Systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Substantial Equivalence
The subject devices are substantially equivalent to the primary predicate devices cleared in K140454 and the additional predicates cleared in K143375 and K143628.

Technological Characteristics
The subject device has equivalent technological characteristics to its predicates presented below through comparison in areas including labeling/indications for use, general design features, function, material, manufacturing process and principle of operation:

- Medtronic Navigated Horizon screwdriver/Taps, K140454 - Primary

Performance Data
Spinal Elements Navigated Instruments have been tested per ASTM F2554 “Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems”. The results of this non-clinical testing show that performance of the Spinal Elements Navigated instruments is sufficient for its intended use and is substantially equivalent to legally marketed devices.

Conclusion
Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject device has been shown to be substantially equivalent to the aforementioned predicate devices cleared by FDA for commercial distribution in the United States.