November 22, 2019

Medtronic Sofamor Danek USA, INC.
Parwinder Singh
Associate Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K192336
Trade/Device Name: Navigated Anterolateral Disc Prep Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 27, 2019
Received: August 28, 2019

Dear Parwinder Singh:

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)*

K192336

Device Name
Naviagted Anterolateral Disc Prep Insturments

Indications for Use *(Describe)*

The Navigated Disc Preparation Instruments are intended to be used to facilitate a discectomy or boney resection during spinal surgery. The Navigated T2 Stratosphere templates are intended to be used to facilitate size selection of vertebral body replacement devices during spinal surgery. The Navigated Capstone™ Trials are intended to be used to facilitate implant size selection of Medtronic intervertebral body fusion devices during spinal surgery. When the Navigated Rotating Shavers are used as trials for Elevate™ Spinal System, they are intended to be used to facilitate implant size selection. The Navigated Probe is intended to be used during pedicle preparations. The Navigated Inserters are intended to be used for the placement of an implant.
Navigated instruments are specifically designed for use with the 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 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.

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510(k) Summary

October 31, 2019

I. Submitter: Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901)396-3133

Contact: Parwinder Singh
Associate Regulatory Affairs Specialist
Telephone Number: (901) 396-3133
Email: parwinder.singh@medtronic.com

II. Device :

Proprietary Trade Name:	Navigated Anterolateral Disc Prep Instruments
Common Name:	Navigated Instruments
Classification Name:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Classification:	Class II
Product Code:	OLO

Purpose: The purpose of this submission is to seek clearance for the Navigated Anterolateral Disc Prep Instruments, utilized with the StealthStation® System.

III. Predicates:

Primary Predicate	Navigated Disc Prep Instruments	K150231, SE. 06/16/2015
Predicate Two	Nav T2 Stratosphere Inserters and Navigated Templates	K191039, SE. 08/26/2019
Predicate Three (Reference)	Nav CD Horizon Solera Screwdrivers, Taps, Iliac Taps, Legacy Taps	K124004, SE. 3/22/2013

This predicate has not been subject to a design-related recall.

IV. Product Description:

The Navigated Anterolateral Disc Prep Instruments are made of high-grade stainless steel as the predicate, per ASTM F899. These instruments are specifically designed for use in procedures where the use of stereotactic surgery may be appropriate to facilitate a discectomy or boney resection during spinal surgery. The instruments are compatible with

Medtronic NavLock trackers and Medtronic single-use sterile spheres to allow a Medtronic computer-assisted surgery system such as the StealthStation® Image Guidance System to track the instruments in the surgical field.

V. Indications for Use:

The Navigated Disc Preparation Instruments are intended to be used to facilitate a discectomy or boney resection during spinal surgery. The Navigated T2 Stratosphere templates are intended to be used to facilitate size selection of vertebral body replacement devices during spinal surgery. The Navigated Capstone™ Trials are intended to be used to facilitate implant size selection of Medtronic intervertebral body fusion devices during spinal surgery. When the Navigated Rotating Shavers are used as trials for Elevate™ Spinal System, they are intended to be used to facilitate implant size selection.

The Navigated Probe is intended to be used during pedicle preparations. The Navigated Inserters are intended to be used for the placement of an implant.

Navigated instruments are specifically designed for use with the 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 a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

VI. Comparison of Technological Characteristics:

The subject Navigated Anterolateral Disc Prep Instruments have the same indications, intended use, fundamental scientific technology, materials, and sterilization method as the previously FDA cleared primary predicate Navigated Disc Prep Instruments (K150231, S.E. 06/16/2015)

VII. Discussion of the Performance Testing:

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The K124004 was used as a comparator for performance testing. The following table summarizes the performance testing completed:

Test	Description
Navigation Accuracy Analysis	Confirmed navigated instrument accuracy.
Navigation Simulated Use	Confirmed navigation system functionality under expected use conditions.
CAD Model Evaluation	Verified that the CAD models are accurately reflected in the application software.
Spine Tools Package Functional Testing	Verified that the Spine Tools package has met the required interface needs of the spine application software.

Verification & Validation	Verified that the instruments function according to their intended use.
Biocompatibility	Verified that the instrument material meets the ASTM standards

VIII. Conclusion:

Based on the supporting information provided in this pre-market notification, the subject Navigated Anterolateral Disc Prep Instruments are substantially equivalent to the primary predicate Navigated Disc Prep Instruments (K150231, S.E. 06/16/2015).