June 9, 2021

Medtronic Sofamor Danek USA, INC.
Alex Underberg
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K211441
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: May 7, 2021
Received: May 10, 2021

Dear Alex Underberg:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211441

Device Name
Navigated Anterolateral Disc Prep Instruments

Indications for Use *(Describe)*
Medtronic Surgical Instruments for use with MAZOR X Stealth™ Edition

Medtronic Surgical Instruments are intended to be used during the preparation and placement of Medtronic implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Surgical Instruments are specifically designed for use with the MAZOR X Stealth™ Edition, 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. Medtronic Surgical Instruments can be navigated or non-navigated manual instruments that may or may not be guided through the MAZOR X Stealth™ Edition Arm Gide. Medtronic surgical drills shall only be used through the MAZOR X Stealth™ Edition arm guides, Medtronic cannulas, and Medtronic drill guides. Some of the Medtronic Surgical Instruments are also compatible with the IPC™ POWEREASE™ System or AO style quick connect drilling motors. An instrument may incorporate a measuring function which has uses as described on the label and the instrument.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211441

Device Name

Navigated Anterolateral Disc Prep Instruments

Indications for Use *(Describe)*

Medtronic Navigated Manual Reusable Instruments for Use with the StealthStation™ System

Medtronic Navigated Surgical Instruments are intended to be used during preparation and placement of Medtronic implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Medtronic Navigated Reusable Instruments can be compatible with various Medtronic spinal implant systems. Navigated surgical 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. An instrument may incorporate a measuring function, which has uses as described on the label and the instruments.

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)

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Section 3: 510(k) Summary

K211441

510(k) Summary

May 7th, 2021

I. Submitter:

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

Contact: Alex Underberg
Regulatory Affairs Specialist
Telephone Number: (901) 344-1443
Email: Alex.R.Underberg@Medtronic.com

II. Device:

Proprietary Trade Name:	Navigated Anterolateral Disc Prep Instruments
Common Name:	Navigated Instruments
Classification Name:	Orthopedic Stereotactic Instrument
Regulation Numbers:	Class II (21 CFR 882.4560)
Classification:	Class II
Product Code:	OLO

III. Predicates:

Primary Predicate	Navigated Disc Prep Instruments (K150231, S.E. 06/16/2015; K203005, S.E. 10/27/2020) Classification: Class II FDA Product Code: OLO
Additional Predicate	Navigated Anterolateral Disc Prep Instruments (K192336, S.E. 11/22/2019)

	Classification: Class II FDA Product Code: OLO

The predicates have not been subject to a design-related recall.

IV. Product Description:

The Navigated Anterolateral Disc Prep Instruments are made of high-grade stainless steel. These instruments are specifically designed for use in procedures where the use of stereotactic surgery may be appropriate. 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™ System or MAZOR X Stealth™ Edition System to track the instruments in the surgical field.

V. Indications for Use:

1. **Medtronic Navigated Manual Reusable Instruments for Use with the StealthStation™ System"**

   Medtronic Navigated Surgical Instruments are intended to be used during preparation and placement of Medtronic implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Medtronic Navigated Reusable Instruments can be compatible with various Medtronic spinal implant systems. Navigated surgical 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. An instrument may incorporate a measuring function, which has uses as described on the label and the instruments.

2. **Medtronic Surgical Instruments for use with MAZOR X Stealth™ Edition**

   Medtronic Surgical Instruments are intended to be used during the preparation and placement of Medtronic implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Surgical Instruments are specifically designed for use with the MAZOR X Stealth™ Edition, 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. Medtronic Surgical Instruments can be navigated or non-navigated manual instruments that may or may not be guided through the MAZOR X Stealth™ Edition Arm Gide. Medtronic surgical drills shall only be used through the MAZOR X Stealth™ Edition arm guides, Medtronic cannulas, and Medtronic drill guides. Some of the Medtronic Surgical Instruments are also compatible with the IPC™ POWEREASE™ System or AO style quick connect drilling motors. An instrument may incorporate a measuring function which has uses as described on the label and the instrument.

VI. Comparison of Technological Characteristics:

The subject Navigated Anterolateral Disc Prep Instruments have an identical intended use, fundamental scientific technology, materials, sterilization method, and compatibilities with StealthStation™ System as the predicate devices. The subject devices are seeking the additional use with MAZOR X Stealth™ Edition System. The use with StealthStation™ System and MAZOR X Stealth™ Edition is identical indications to the primary predicate Navigated Disc Prep Instruments (K150231, S.E. 06/16/2015; K203005, S.E. 10/27/2020).

The subject Navigated Anterolateral Disc Prep Instruments were previously cleared within (K192336, S.E. 11/22/2019) and are not undergoing any design changes.

VII. Discussion of the Performance Testing:

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The following table summarizes the performance testing that was rationalized or completed:

Test	Description
Navigation Accuracy Analysis	Confirmed navigated instrument accuracy
CAD Model Verification	Confirmed CAD models are accurately reflected in the application software
Tools Package Functional Verification	Provides confirmation that the Spine tools package has met the required interface needs of the spine application software
NAV Simulated Use	No new testing completed
Anatomical Simulated Use	No new testing completed

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 predicate devices.