December 8, 2020

Medtronic Sofamor Danek USA, INC.
Erikka Edwardsen
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K203291
Trade/Device Name: CD Horizon Spinal System Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 6, 2020
Received: November 9, 2020

Dear Erikka Edwardsen:

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)*

K203291

Device Name
CD Horizon™ Spinal System Instruments

Indications for Use *(Describe)*

Indications for Use Medtronic Navigated Reusable Instruments for use with StealthStation™ and IPC™ POWEREASE™ Systems

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable 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. Medtronic Navigated Reusable Instruments are also compatible with the IPC™ POWEREASE™ System.

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 Guide. 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.

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510(k) Summary

November 6, 2020

I. Submitter:

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

Contact: Erikka Edwardsen
Sr Regulatory Affairs Specialist
Telephone Number: (901) 399-2485
Email: rikka.r.edwardsen@medtronic.com

II. Device:

Proprietary Trade Name:	CD Horizon™ Spinal System
Common Name:	Stereotaxic Instrument, Navigated Instruments
Classification Name:	Stereotaxic Instrument
Regulation Numbers:	Class II (21 CFR 882.4560)
Classification:	Class II
Product Code:	OLO

III. Predicates:

Predicate:

- Primary Predicate: CD Horizon™ SOLERA Instruments (K140454, S.E. 05/22/2014)
- Additional Predicate: CD Horizon™ Spinal System Instruments (K182121, S.E. 11/02/2018)

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

IV. Product Description:

The subject CD Horizon™ Spinal System drivers are non-sterile instruments that may be used during placement of various Medtronic screws during spinal surgery. The Medtronic

instruments are made from materials commonly used in orthopedic and neurological procedures which meet available national or international standards specifications.
The subject CD Horizon™ Spinal System drivers are compatible with POWEREASE, Medtronic NavLock trackers and Medtronic single-use sterile spheres to allow a Medtronic computer-assisted surgery system to track the instruments in the surgical field.

V. Indications for Use

Medtronic Navigated Reusable Instruments for use with StealthStation™ and IPC™ POWEREASE™ Systems

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable 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. Medtronic Navigated Reusable Instruments are also compatible with the IPC™ POWEREASE™ System.

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 Guide. 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 CD Horizon™ instruments are intended to be used during the placement of Medtronic screws during spinal surgery. The subject devices have similar designs, principle of operation, fundamental scientific technology, material, intended use, as the predicate devices and incorporate the same design features to enable navigation and compatibility and use with IPC™ POWEREASE™ System when desired.

The only change to the subject CD Horizon™ Spinal System drivers (K182121, S.E. 11/02/2018) is the expanded indications. Expanding the indications will provide surgeons additional driver options during procedures currently enabled on the StealthStation™ system. The subject drivers will have the same indications for use as the CD Horizon Solera™ drivers (K140454, S.E. 05/22/2014). The devices continue to be compatible with the Mazor X Stealth Edition, NavLock Trackers, the IPC POWEREASE System (K111520, S.E. 10/26/2011) quick connect manual handles and CD Horizon Spinal System bone screws

VII. Discussion of the Performance Testing:

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The test results show that the subject device and the predicate device are equivalent.

Test	Description
Navigation Accuracy Testing	Confirmed navigated instrument accuracy
CAD Model Verification	Confirm the driver's CAD models are accurately reflected in the application software.

Tools Package Functional Verification Testing	Provides confirmation that the Spine tools package has met the required interface needs of the spine application software.
Navigated Simulated Use	Validate that the design outputs meet the requirements associated with customer needs.
Anatomical Simulated Use Testing	User needs are satisfied by performing simulated testing per the instructions outlined in the surgical techniques

VIII. Conclusion:

Based on the supporting information provided in this pre-market notification, the subject CD Horizon™ Spinal System Drivers are substantially equivalent to CD HORIZON SOLERA Instruments (K140454, S.E. 05/22/2014)