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

November 2, 2018

Re: K182121
Trade/Device Name: CD HORIZON Spinal System Instruments for use with MAZOR X Stealth Edition
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 31, 2018
Received: November 1, 2018

Dear Erikka Edwardsen:

This letter corrects our substantially equivalent letter of November 2, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2018.11.02 16:01:49 -04'00'

For
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K182121

Device Name

CD HORIZON Spinal System Instruments for use with MAZOR X Stealth™ Edition

Indications for Use *(Describe)*

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 Arm Guide. Medtronic surgical drills shall only be used through the MAZOR X arm guides, Medtronic cannulas, and Medtronic drill guides. Some of the Medtronic Surgical Instruments are also compatible with the IPC™ POWEREASE™ System. An instrument may incorporate a measuring function which has uses as described on the label and the instrument.
DO NOT IMPLANT 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)

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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"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."

K182121

510(k) SUMMARY

October 31, 2018

I. Company: Medtronic Sofamor Danek, USA Inc.
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Memphis, TN 38132
Telephone Number: (901) 396-3133

Contact: Erikka Edwardsen
Senior Regulatory Affairs Specialist
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Shweta Sharma
Principal Regulatory Affairs Specialist
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Email: shweta.s.sharma@medtronic.com

II. Proprietary Trade Name: CD HORIZON™ Spinal System Instruments for use with MAZOR X Stealth Edition

Common Name: Stereotaxic Instrument, Navigated Instruments

Classification Name: Stereotaxic Instrument (21 CFR 882.4560)

Classification: Class II

Product Code: OLO

III. Predicate Devices:

Primary Predicate:
Navigated CD HORIZON™ SOLERA™ Spinal System (K140454, S.E. 05/22/2014)

Reference Predicates:

CD HORIZON™ BALLAST™ Spinal System (K153442, S.E. 02/18/2016)

MAZOR X (K163221, S.E. 04/04/2017)

Navigated CD HORIZON™ SOLERA™ Spinal System (K124004, S.E 03/22/2013)

IPC™ POWEREASE™ System (K111520, S.E. 10/26/2011)

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

IV. Device Description:

The CD HORIZON™ Spinal System surgical instruments are non-sterile or sterile, single or re-usable instruments that may be used during the preparation and placement of various Medtronic spinal implants during spinal surgery. The subject instruments are made of a variety of materials commonly used in orthopedic and neurological procedures which meet available national or international standards specifications. Single-use Medtronic Surgical instruments should never be reused under any circumstances.

The CD HORIZON™ instruments are specifically designed for use in spinal procedures with MAZOR X Stealth™ Edition. The instruments can be navigated or non-navigated manual instruments that may or may not be guided through the MAZOR X Arm Guide. Some instruments (e.g. drills, drivers, taps etc.) are also compatible with Medtronic's IPC™ POWEREASE™ System when connected to the POWEREASE™ Driver, these CD HORIZON™ instruments may or may not be guided through the MAZOR X Arm Guide. Medtronic surgical drills shall only be used through the MAZOR X arm guides, cannulas, and drill guides. Placing Medtronic single-use sterile spheres on each of the NavLock™ Tracker passive stems allow MAZOR X Stealth™ Edition to track the Medtronic instruments in the surgical field.

V. Indications for Use:

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 Arm Guide. Medtronic surgical drills shall only be used

through the MAZOR X arm guides, Medtronic cannulas, and Medtronic drill guides. Some of the Medtronic Surgical Instruments are also compatible with the IPC™ POWEREASE™ System. An instrument may incorporate a measuring function which has uses as described on the label and the instrument.

DO NOT IMPLANT THE INSTRUMENTS

VI. Comparison of the Technological Characteristics with the Predicate Device:

The CD HORIZON™ instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery and are specifically designed for use with the MAZOR X Stealth™ Edition. Like the predicate devices, the subject instruments work through an arm guide for trajectory guidance and attach to NavLock™ Trackers to allow for optical navigation. 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, arm guide compatibility and use with the IPC™ POWEREASE™ System, when desired.

The only difference between the subject and predicate devices is, the predicate devices are navigated on the Stealth ™ Station and the predicate devices are navigated via the MAZOR X™ Stealth Edition.

VII. Performance Data:

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

Test	Description
Navigation Accuracy Analysis	Confirmed navigated instrument accuracy
Anatomical Simulated Use	Confirmed instrument functionality under expected use conditions
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
Navigation Software Module Instrument Functional Testing	Verified that the instrument attributes are correctly implemented in the navigation software module.

VIII. Conclusions

The CD HORIZON™ Instruments for use with the MAZOR X Stealth™ Edition have shown through comparison and testing to be substantially equivalent to the identified predicate devices.