February 9, 2022

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

Re: K214011
Trade/Device Name: Catalyft™ PL Expandable Interbody System Navigated Instruments, Anteralign™ TL Spinal System with Titan nanoLOCK™ Surface Technology Navigated Instruments, and CD Horizon™ Solera™ Voyager™ Spinal System Navigated, Guided, and Powered Drivers
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, MAX, OVD, HBE
Dated: January 7, 2022
Received: January 10, 2022

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K214011

Device Name
Catalyft™ PL Expandable Interbody System Navigated Instruments, Anteralign™ TL Spinal System with Titan nanoLOCK™ Surface Technology Navigated Instruments, and CD Horizon™ Solera™ Voyager™ Spinal System Navigated, Guided, and Powered Drivers

Indications for Use *(Describe)*

Medtronic Surgical Instruments are intended to be used during preparation and placement of Medtronic implants during spinal surgery to assist 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 medical conditions 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. Medtronic cannulas may or may not be used with Midas Rex™ attachments and tools.

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.

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510(k) Summary

February 8th, 2022

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:

1. Catalyft™ PL Expandable Interbody System Navigated Instruments
2. Anteralign™ TL Spinal System with Titan nanoLOCK™ Surface Technology Navigated Instruments
3. CD Horizon™ Solera™ Voyager™ Spinal System Navigated, Guided, and Powered Drivers

Common Name: Stereotactic Instruments, Navigated Instruments

Classification Name: Orthopedic Stereotactic Instrument

Regulation Numbers: Class II (21 CFR 882.4560)

Classification: Class II

Product Code:
Catalyft™ PL: OLO, MAX
Anteralign™ TL: OLO, MAX, OVD
CD Horizon™ Solera™ Voyager™: OLO, HBE

III. Predicates:

Primary Predicate	CD Horizon™ Spinal System ModuLeX Instruments for use with MAZOR X Stealth Edition (K211596, S.E. 06/23/2021)

	Classification: Class II FDA Product Code: OLO
Additional Predicate	Catalyft™ PL Expandable Interbody System Navigated Instruments (K210425, S.E. 05/24/2021) Classification: Class II FDA Product Code: OLO, MAX
Additional Predicate	Anteralign™ TL Spinal System with Titan nanoLOCK™ Surface Technology Navigated Instruments (K212524, S.E. 12/08/2021) Classification: Class II FDA Product Code: OLO, MAX, OVD

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

IV. Product Description:

Catalyft™ PL Expandable Interbody System Navigated Instruments

The Catalyft™ PL Expandable Interbody System navigated instruments consist of an Inserter (Outer), Inserter Inner Sleeve, Trials, a NAV Verification Tool, and Navigated Rotating Shavers that were cleared in K210425. These instruments are navigated instruments manufactured from stainless steel and are currently cleared for use in procedures where the use of stereotaxic surgery may be appropriate with the StealthStation™ System (K050438, S.E. 06/02/2005; K201189, S.E. 05/29/2020). Per this 510(k) submission, Medtronic is seeking clearance of the subject devices to also be navigated with MAZOR X™ (K182077, S.E. 11/02/2018; K203005, S.E. 10/27/2020) with the devices remaining compatible with StealthStation™ System.

Please note that the Navigated Rotating Shavers were previously cleared for use on MAZOR X™ (K203005, S.E. 10/27/2020), and per this 510(k) submission, the Rotating Shavers can be used for disc prep and to trial for Catalyft™ PL on MAZOR X™.

Anteralign™ TL Spinal System with Titan nanoLOCK™ Surface Technology Navigated Instruments

The Anteralign™ TL navigated instruments consist of an Inserter and Trials that were originally cleared in K212524. These instruments are navigated instruments manufactured from stainless steel and are currently cleared for use in procedures where the use of stereotaxic surgery may be appropriate with the StealthStation™ System (K050438, S.E. 06/02/2005; K201189, S.E. 05/29/2020). Per this 510(k) submission, Medtronic is seeking clearance of the subject devices to also be navigated with MAZOR X™ (K182077, S.E. 11/02/2018; K203005, S.E. 10/27/2020) with the devices remaining compatible with StealthStation™ System.

CD Horizon™ Solera™ Voyager™ Navigated, Guided, and Powered Drivers

The CD Horizon™ Solera™ Voyager™ Spinal System navigated instruments consists of new Drivers, which will be manufactured from stainless-steel. Medtronic is seeking clearance of the Drivers to be Navigated and Trajectory Guided via MAZOR X™ (K182077, S.E. 11/02/2018; K203005, S.E. 10/27/2020) and Powered via IPC™ POWEREASE™ System (K111520, S.E. 10/26/2011; K123270, S.E. 01/11/2013). To enable trajectory guidance compatibility, the Drivers have been designed to work with the MAZOR X™ Arm Guides. To enable power, the Drivers may also be attached to the POWEREASE™ Driver (K111520, S.E. 10/26/2011).

V. Indications for Use:

Medtronic Surgical Instruments for use with MAZOR X Stealth™ Edition

Medtronic Surgical Instruments are intended to be used during preparation and placement of Medtronic implants during spinal surgery to assist 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 medical conditions 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. Medtronic cannulas may or may not be used with Midas Rex™ attachments and tools.

VI. Comparison of Technological Characteristics:

The Catalyft™ PL and Anteralign™ TL previously cleared navigated 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 compatibility with the MAZOR X™ system, which is identical to the Primary Predicate.

The new CD Horizon™ Solera™ Voyager™ Drivers have been designed with features to enable compatibility with the MAZOR X™ system, MAZOR X™ arm guide, and IPC™ POWEREASE™ System, which is identical to the primary predicate. The Drivers have an identical intended use, fundamental scientific technology, materials, and sterilization method as the predicate devices.

VII. Discussion of the Performance Testing:

Testing was rationalized or completed new to ensure the functionality and compatibility of the identified Medtronic products when used with the Mazor X™ system. 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	To demonstrate that the navigated-specific procedural steps can be executed to navigate a spinal procedure
Anatomical Simulated Use	To validate that the product appropriately satisfies the user needs by performing simulated use testing per the instructions outlined in the surgical technique

*Please note the tests mentioned above were evaluated for all systems

VIII. Conclusion:

Based on the supporting information provided in this pre-market notification, the subject instruments are substantially equivalent to the predicate devices.