September 29, 2022

Medtronic Sofamor Danek USa, Inc.
Elizabeth Hamilton
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K222383
Trade/Device Name: Anteralign™ LS Spinal System with Titan nanoLOCK™ Surface Technology MAZORX Stealth(TM) Edition
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 30, 2022
Received: September 1, 2022

Dear Elizabeth Hamilton:

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)*
K222383

Device Name
Anteralign(TM) LS Spinal System with Titan nanoLOCK(TM) Surface Technology Navigated Instruments with Mazor X(TM) (Stealth Edition)

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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K222383 - 510(k) SUMMARY
MEDTRONIC Sofamor Danek
23 September 2022

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)399-3395 Fax: (901) 346-9738
Primary Contact	Elizabeth Hamilton Sr. Regulatory Affairs Specialist Email : elizabeth.c.hamilton@medtronic.com
Alternate Contact:	Raphael McInnis Sr. Regulatory Affairs Manager Email : raphael.mcinniss@medtronic.com
Date Prepared:	23 September 2022
Name of Device	Anteralign™ LS Spinal System with Titan nanoLOCK™ Surface Technology Navigated Instruments with MAZOR X™ (Stealth™ Edition)
Common Name	Navigated Instruments
Classification Name	Stereotaxic Instruments (21 CFR 882.4560)
Regulatory Class	Class II
Product Code	OLO
Predicate Devices	Primary Predicate -Anteralign™ TL Spinal System with Titan nanoLOCK™ Surface Technology Navigated Instruments Compatible with MAZOR X™ system (Stealth™ Edition) (K214011, S.E. 02/09/2022)

Description of Device

The Anteralign™ LS Navigated Reusable Surgical Instruments are spine preparation instruments made of high-grade stainless steel. The subject navigated instruments consist of existing navigated trials and a navigated interbody inserter, which were recently cleared in K221180, S.E. 5/25/22 for use in Anteralign Interbody System procedures where the use of stereotaxic surgery may be appropriate with the StealthStation™ System. Per this 510(k) submission, Medtronic is seeking clearance of the navigated instruments to also be compatible with the MAZOR X™ Stealth Edition. The instruments are compatible with NavLock trackers and Medtronic single -use sterile spheres to allow the Medtronic computer-assisted surgery system, such as the Stealth Station System and MAZOR X™ System (Stealth™ Edition), to track the instruments in the surgical field.

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.

Comparison of Technological Characteristics with Predicate Devices

The subject Anteralign™ LS Spinal System with Titan nanoLOCK™ Surface Technology Navigated Instruments have an identical intended use, fundamental scientific technology, sterilization method, materials, and compatibilities with StealthStation™ System as the recently cleared predicate devices listed above. The subject devices are seeking compatibility with MAZOR X™ system, which is identical to the Primary Predicate's Indications for Use.

Performance Data Previous testing completed on the predicate device was leveraged for the subject devices. The subject instruments do not represent a new worst-case and the testing previously performed for the predicate devices is deemed applicable for the subject devices as there are no changes to the methods in which these instruments are used within the procedure. The following table summarizes the performance testing that was rationalized:

Test	**Description**
Navigation Accuracy Analysis	Confirmed navigated instrument accuracy
Anatomical Simulated Use	Confirmed instrument functionality under expected use conditions
Navigated Simulated Use	Confirmed navigation system functionality under expected use conditions

Conclusion

Based on the information contained in this submission, Medtronic believes that the subject instruments are substantially equivalent to the predicate device.