July 18, 2023

Medtronic Sofamor Danek Inc
Diamond Wallace
Sr. Regulatory Affairs Specialist
2600 Sofamor Danek Drive
Memphis, Tennessee 38132

Re: K230716
Trade/Device Name: Robotic Graft Delivery Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 13, 2023
Received: March 15, 2023

Dear Diamond Wallace:

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,

Shumaya Ali -S

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)*
K230716

Device Name
Medtronic Surgical Instruments for use with Mazor X 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 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.
Do not implant instruments.
Medtronic does not and cannot warrant the use of these instruments nor any of the component parts upon which repairs have been made or attempted, except as performed by Medtronic or an authorized Medtronic repair representative. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

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

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

Contact: Raphael McInnis

Telephone number: (901) 396-3133
Email: raphael.mcinnis@medtronic.com

II. Proprietary Trade Name: Robotic Graft Delivery Instruments

Common Name: Stereotaxic Instrument

Classification Name: Stereotaxic Instrument (21 CFR 882.4560)

Classification: Class II

Product Code: OLO

III. Predicate Devices:

Primary Predicate:
CD HORIZON Spinal System Non-navigated, Guided Instruments
(K182121, S.E 11/08/2018)

Reference Predicate:

Mazor X System (Mazor X Stealth Edition)
(K230064 S.E. 04/07/2023)

Reference Predicate:
Graft Gun (Medtronic Class I Exempt)

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

IV. Device Description:

The robotic graft delivery instruments are non-sterile re-usable instruments that may be used during the preparation and placement of various graft material during spinal surgery.

The subject instruments are made of a medical grade stainless steel commonly used in orthopedic procedures, which meet available national or international standards specifications. The robotic graft delivery instruments are intended to be used when preparing and placing graft material during spinal surgery. To enable trajectory guidance compatibility of the surgical instruments with the MAZOR X Stealth™ Edition System, the instrument dimensions have been designed to work through the MAZOR X arm guides. The instruments will be provided non-sterile and reusable.

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 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.

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

The robotic graft delivery instruments are intended to be used during the preparation and placement of graft material during spinal surgery and are specifically designed for use with trajectory guidance through the robotic arm. Like the predicate device, the subject instruments work through an arm guide for trajectory guidance. The subject instruments have similar designs, principle of operation, fundamental scientific technology, material, intended use, as the primary predicate device and incorporate the similar design features to

enable arm guide compatibility. Additionally, the subject instruments have similar designs and fundamental scientific technology as the reference predicate.

The subject instruments are assembled and placed through a cannula the same as the primary predicate device to allow access to the surgical site through the arm guide. Unlike the primary predicate, the subject instruments are used to deliver graft material to the surgical site similar to the reference predicate,

VII. Performance Data:

The following testing was performed on the Robotic Graft Delivery instrument to ensure the functionality and compatibility with the identified Medtronic MAZOR X Stealth Arm Guide. The table below provides a summary of the performance testing completed:

Test	Description
Anatomical Simulated Use	Confirmed instrument functionality under expected use conditions
Mechanical Guidance Accuracy (Surgical Tools Mechanical Tolerance)	Confirmed that the subject instruments have a maximum radial deviation within the allowable surgical tool mechanical tolerance at the bone entry surface. This is a component of the total robotic guidance trajectory accuracy.
Depth Control Analysis	Confirmed the graft delivery instruments engage facet defect created by Mazor X Stealth Edition facet decortication tools.

VIII. Conclusions

The robotic graft delivery instruments have shown through comparison and testing to be substantially equivalent to the identified predicate devices.