Medtronic Navigation
Jainam Shah
Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

November 2, 2018

Re: K182104
Trade/Device Name: NavLock Trackers, Robotic Reference Frame
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 2, 2018
Received: August 3, 2018

Dear Jainam Shah:

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 15:53:43 -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)*

K182104

Device Name
NavLock Trackers

Indications for Use *(Describe)*

The NavLock™ Trackers are intended to enable navigation of Medtronic instrumentation used during spinal fusion and interbody procedures with the MAZOR X Stealth™ Edition system. The NavLock™ Trackers should only be used with Medtronic instruments on the MAZOR X Stealth™ Edition system.

The Robotic Reference Frame is an accessory to the MAZOR X Stealth Edition system and is intended to enable navigation during spinal fusion and interbody procedures that utilize the MAZOR X Stealth Edition system

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K182104

Device Name
Robotic Reference Frame

Indications for Use *(Describe)*
The Robotic Reference Frame is an accessory to the MAZOR X Stealth™ Edition system and it is intended to enable navigation during spinal fusion and interbody procedures that utilize the MAZOR X Stealth™ Edition system.

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)

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K182104

510(k) Summary

July 31, 2018

I. Company: Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027
Telephone Number: (720) 890-3200

Contact: Jainam Shah
Regulatory Affairs Specialist
Telephone Number: (720) 890-2595
Fax: (720) 890-3500
Email: jainam.shah@medtronic.com

II. Proprietary Trade Name: NavLock™ Trackers; Robotic Reference Frame

III. Common Name: Orthopedic Stereotaxic Instrument

IV. Classification Name: Stereotaxic Instrument (21 CFR 882.4560)

V. Classification: Class II

VI. Product Code: OLO

VII. Product Description:
The NavLock trackers are compatible with the MAZOR X Stealth™ Edition system. The NavLock Trackers are used in conjunction with various navigated spine instrumentation for optical navigation. To enable navigation compatibility, the proximal ends of the instruments are designed to fit into the NavLock Trackers for optical navigation. The subject NavLock Trackers have posts to affix reflective spheres, which are visible to the MAZOR X Navigation camera as a means of tracking the position of the attached surgical instrument.
The Robotic Reference Frame is an accessory to the MAZOR X Stealth™ Edition system. The Robotic Reference Frame has posts to affix reflective spheres, which are visible to the MAZOR X Navigation camera for tracking location during navigated procedures.

VIII. Indications for Use:
The NavLock Trackers are intended to enable navigation of Medtronic instrumentation used during spinal fusion and interbody procedures with the MAZOR X Stealth™ Edition system. The NavLock Trackers should only be used with Medtronic instruments on the MAZOR X Stealth™ Edition system.

The Robotic Reference Frame is an accessory to the MAZOR X Stealth™ Edition system intended to enable navigation during spinal fusion and interbody procedures that utilize the MAZOR X Stealth™ Edition system.

IX. Identification of Legally Marketed Devices (Predicate Devices):

NavLock Trackers (K171267, S.E. 07/03/2017). This predicate has not been subject to any recall. This predicate is the primary predicate for this submission.

The following devices have been added as reference devices in this submission:

- SteathStation® S8 Spine Software v1.0.0 (K170011, S.E. 05/01/2017)
- SteathStation® S8 System (K162309, S.E. 03/31/2017).

X. Comparison of the Technological Characteristics:

The subject devices under this submission consist of the NavLock trackers and the Robotic Reference Frame. Both the subject devices are stereotaxic instruments intended to enable navigation during stereotactic spinal procedures that utilize the MAZOR X Stealth™ Edition system. A comparison of the technological characteristics is provided below:

Feature	**Subject Devices (NavLock Trackers and Robotic Reference Frame)**	**NavLock Trackers, K171267, S.E. 07/03/2017**
Product Code	OLO	OLO
Operating Principle (Tracking Method)	Optical (infra-red)	Optical (infra-red)
Intended Use	The subject devices are intended to enable navigation during stereotactic spinal procedures that utilize the MAZOR X Stealth™ Edition system.	The NavLock trackers are intended to enable navigation of Medtronic instrumentation during stereotactic spinal procedures that utilize the Medtronic StealthStation surgical navigation system.
Indications for Use	The NavLock Trackers are intended to enable navigation of Medtronic instrumentation used during spinal fusion and interbody procedures with the MAZOR X Stealth™ Edition system. The NavLock™ Trackers should only be used with Medtronic instruments on the Medtronic MAZOR X Stealth™ Edition system.	The NavLock Trackers are intended to enable navigation of Medtronic instrumentation used during spinal fusion and interbody procedures with the Medtronic StealthStation surgical navigation system. The NavLock Trackers should only be used with Medtronic instruments.

Feature	Subject Devices (NavLock Trackers and Robotic Reference Frame)	NavLock Trackers, K171267, S.E. 07/03/2017
	The Robotic Reference Frame is an accessory to the MAZOR X Stealth™ Edition system and it is intended to enable navigation during spinal fusion and interbody procedures that utilize the MAZOR X Stealth™ Edition system.	
Sterilization Method	Non-Sterile, Reusable, Steam Sterilized	Non-Sterile, Reusable, Steam Sterilized

The difference in the indications for use between the subject devices and the predicate device is that the subject devices are compatible with the MAZOR X Stealth™ Edition system. The test data included with this submission supports the compatibility of the subject devices with the MAZOR X Stealth™ Edition system.

XI. Discussion of the Performance Testing:

Testing conducted to demonstrate equivalency of the subject device to the predicate device is summarized as follows:

Test	Description
Navigational Accuracy Analysis	Provides confirmation that the subject devices satisfy the necessary navigational accuracy requirements.
Accelerated Life Functionality	Tested functionality after multiple reprocessing cycles (cleaning and sterilization) and repeated use. Provides confirmation that the product remains functional throughout its intended useful life.

XII. Conclusions

The subject devices have shown through comparison to be substantially equivalent to the identified predicate device.