June 18, 2020

Medtronic Navigation
Taylor West
Senior Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, California 80027

Re: K201327
Trade/Device Name: NavLock Trackers
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 18, 2020
Received: May 19, 2020

Dear Taylor West:

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, 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)*
K201327

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 Medtronic systems utilizing STEALTH™ Technology. The NavLock™ Trackers should only be used with Medtronic instruments on Medtronic systems utilizing STEALTH™ Technology.

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

May 18, 2020

I. Company:

Medtronic Navigation
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Louisville, CO 80027
Telephone Number: (720) 890-3200

Contact: Taylor Gold West, MBA (Primary)
Senior Regulatory Affairs Specialist
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Rishi Sinha (Alternate)
Senior Regulatory Affairs Manager
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II. Proprietary Trade Name: NavLock™ Trackers

III. Common Name: Orthopedic Stereotaxic Instrument

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

V. Classification: Class II

VI. Product Code: OLO

VII. Primary Predicate: Navlock™ Trackers, K182104
Additional Predicate: Navlock™ Trackers, K171267

VIII. Product Description:
The NavLock™ Trackers are compatible with StealthStation™ Systems and Mazor X STEALTH™ Edition and 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 NavLock™ Trackers have posts to affix reflective spheres, which are visible to the StealthStation camera as a means of tracking the position of the attached surgical instrument.

IX. Indications for Use:
The NavLock™ Trackers are intended to enable navigation of Medtronic instrumentation used during spinal fusion and interbody procedures with Medtronic systems utilizing STEALTH™ Technology. The NavLock™ Trackers should only be used with Medtronic instruments on Medtronic systems utilizing STEALTH™ Technology.

X. Comparison of the Technological Characteristics:

There have been no changes to the technological characteristics of the NavLock™ Trackers since the clearance of the Medtronic NavLock™ Trackers in K182104.

Feature	**Subject Device, NavLock™ Trackers**	**NavLock ™ Trackers, K182104**	**NavLock™ Trackers, K171267**
Product Code	OLO	OLO	OLO
Operating Principle (Tracking Method)	Optical (infra-red)	Optical (infra-red)	Optical (infra-red)
Intended Use	The subject devices are intended to enable navigation during stereotactic spinal procedures that utilize STEALTH™ Technology.	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 Medtronic systems utilizing STEALTH™ Technology. The NavLock™ Trackers should only be used with Medtronic instruments on Medtronic systems utilizing STEALTH™ Technology.	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 Device, NavLock™ Trackers	NavLock ™ Trackers, K182104	NavLock™ Trackers, K171267
Navigational System Accuracy Analysis	System level accuracy testing was demonstrated on the Navlock™ Trackers for use with StealthStation™ Systems (K171267) and MAZOR X Stealth™ Edition (K182104). Worst-case test configurations using StealthStation™ Software met the criteria of ≤2.0 mm positional error and ≤2.0° trajectory error. Rationale has been provided for the subject Navlock™ Black and Blue Trackers.	Utilizing worst-case test configurations, subject NavLock™ Tracker (NavLock™ Blue) and the Robotic Reference Frame were tested with the MAZOR X Stealth™ Edition software application and the overall test results met the criteria of ≤2.0 mm positional error and ≤2.0° trajectory error.	Utilizing worst-case test configurations, predicate NavLock™ Tracker (NavLock™ Orange)** was tested with StealthStation™ S8 Spine Software application and the overall test results met the criteria of ≤2.0 mm positional error and ≤2.0° trajectory error.
Sterilization Method	Non-Sterile, Reusable, Steam Sterilized	Non-Sterile, Reusable, Steam Sterilized	Non-Sterile, Reusable, Steam Sterilized

XI. Discussion of the Performance Testing:

There have been no significant design changes to the NavLock™ Trackers since clearance in K182104. Therefore, performance testing is not needed to demonstrate substantial equivalence in the current submission.

XII. Conclusions

The NavLock™ Black and Blue Trackers have shown through comparison to be substantially equivalent to the identified predicate devices.