DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medtronic Navigation
Nicole Zimmerman
Associate Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

July 3, 2017

Re: K171267
Trade/Device Name: NavLock Trackers
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 28, 2017
Received: May 1, 2017

Dear Nicole Zimmerman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171267

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 Medtronic StealthStation surgical navigation system. The NavLock™ Trackers should only be used with Medtronic instruments.

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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K171267

510(k) Summary

April 28, 2017

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

Contact: Nicole Zimmerman
Associate Regulatory Affairs Specialist
Telephone Number: (720) 890-2342
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Email: nicole.r.zimmerman@medtronic.com

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. Product Description:
The NavLock Trackers are compatible with the StealthStation Systems 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.

VIII. Indications for Use:
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.

IX. Identification of Legally Marketed Devices (Predicate Devices):
Medtronic Navigated Taps and Screwdrivers (K124004)

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 Navigated Taps and Screwdrivers in K124004.

Various navigated spine instruments that are compatible with the NavLock Trackers have been released since the original clearance but the NavLock Tracker technology has not changed.

XI. Discussion of the Performance Testing:

There have been no significant design changes to the NavLock Trackers since K124004. As such performance testing is not needed to demonstrate substantial equivalence in the current submission. Testing conducted to support the release of NavLock Trackers compatible instrumentation is summarized as follows:

Test	Description
Navigation Accuracy	Verifies 2D and 3D navigational accuracy of the subject instruments with respect to navigational accuracy requirements
Anatomical Simulated Use	Validates that the product appropriately satisfies the user needs by performing simulated use testing per the instructions outlined in the surgical technique.
Navigation Simulated Use	Demonstrates that the navigation-specific procedural steps can be executed to navigate a spinal procedure.
CAD Model Evaluation	Confirms the instrument CAD models are accurately reflected in the application software compared to the physical instrument.
Implant/Instrument Mating Conditions	For instruments that navigate placement of an implant, verifies design requirements associated with assembly, fit, and function of the navigated instruments with the implant system
Software/Instrument Integration Functional Testing	Confirms that the spine tools package has met the required interface needs of the spine application software with predetermined test items such as installation, system configuration, tool verification and functionality in the software application

XII. Conclusions

The NavLock Trackers have shown through comparison to be substantially equivalent to the identified predicate device.