K124004

510(k) Summary

February 14, 2012

MAR 2 2 2013

I. **Company**: Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: 720-890-3200
Fax Number: 720-890-3500

Contact: Michael Blasco
Principal Regulatory Affairs Specialist

II. **Proprietary Trade Name**: Navigated CD HORIZON® SOLERA™ Screwdrivers, CD HORIZON® SOLERA™ Taps, CD HORIZON® SOLERA™ Iliac Taps and CD HORIZON® LEGACY™ Taps

III. **Common Name**: Stereotaxic Instrument

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

V. **Classification**: Class II (21 CFR 882.4560)

VI. **Product Code**: OLO

VII. **Product Description:**
The Navigated Taps and Screwdrivers are surgical instruments intended to be used during the preparation and placement of Medtronic screws during spinal surgery and are specifically designed for use with the StealthStation® System. The Navigated Taps and Screwdrivers attach to the Medtronic NavLock™ Tracker, which allows for optical tracking of the surgical instrument. They are designed for use with the Medtronic CD HORIZON® LEGACY™ and CD HORIZON® SOLERA™ screw systems. As described in the instructions for use, the instruments may also be used with the Medtronic IPC® POWEREASE™ System and NIM-ECLIPSE® System.

VIII. **Indications for Use:**
The Navigated Taps and Screwdrivers are intended to be used during the preparation and placement of Medtronic screws during spinal surgery and are specifically designed for use with the StealthStation® System, 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 the 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.

IX. Identification of Legally Marketing Devices (Predicate Devices)

- StealthStation System Update (K050438)
- IPC® POWEREASE™ System (K111520)

X. Comparison of the Technological Characteristics:

Item	Subject Devices	Predicate Devices
Indications for Use	The Navigated Taps and Screwdrivers are intended to be used during the preparation and placement of Medtronic screws during spinal surgery and are specifically designed for use with the StealthStation® System, 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 the 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.	***Working Ends Compatible with the POWEREASE™ System – K111520*** The working ends are intended for drilling, tapping, or driving screws during spinal surgery, including open and minimally invasive procedures. ***StealthStation System Update - K050438*** The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System 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 the 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. For the optical-based and EM-based system, example procedures include, but are not limited to: Spinal Procedures: Spinal Implant Procedures, such as Pedicle Screw Placement
Operating Principle (Tracking Method)	Identical	***StealthStation System Update - K050438*** Optical (infra-red)
Materials – Taps	Identical	***Working Ends Compatible with the POWEREASE™ System – K111520*** 455 SS
Materials – Screwdrivers	Identical	***Working Ends Compatible with the POWEREASE™ System – K111520*** 455 SS (shaft) and 17-4 SS (sleeve)
Sterilization Method	Identical	***Working Ends Compatible with the POWEREASE™ System – K111520*** Steam sterilization

The subject devices have the same intended use and technological characteristics as the predicate devices.

XI. Discussion of the Performance Testing

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The following table summarizes the performance testing completed:

Test	Description
Accuracy	Tested navigated instrument accuracy in both 2D and 3D space.
Accelerated Life Functionality	Tested navigated instrument functionality after multiple reprocessing cycles (cleaning and sterilization), simulating environmental exposure under expected use conditions.
Simulated Use	Tested navigated instruments according to the user's needs and intended use.
Shipping	Tested navigated instruments after simulated shipping conditions.
CAD Model Testing	Verified that the CAD models are accurately reflected in the application software.
Cleaning Verification	Verified that the product can be effectively cleaned using automated and manual methods.
Spine Tools (Toolcards)	Verified that the Spine tools package has met the required interface needs of the spine application software.

XII. Conclusions

The Navigated Taps and Screwdrivers have been shown through comparison and testing to be substantially equivalent to the identified predicate devices.

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, Incorporated
% Mr. Michael Blasco
Principal Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

March 22, 2013

Re: K124004
Trade/Device Name: Navigated CD HORIZON® SOLERA™ Screwdrivers, CD HORIZON® SOLERA™ Taps, CD HORIZON® SOLERA™ Iliac Taps and CD HORIZON® LEGACY™ Taps
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 21, 2012
Received: December 26, 2012

Dear Mr. Blasco:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K124004

Device Name:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.03.22 12:59:34 -04'00' for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K124004