510(k) Summary

May 2013

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

AUG 14 2013

Contact: Regina Holmes
Sr. Regulatory Affairs Specialist
Telephone: (901) 396-3133
Fax: (901) 346-9738

II. **Proprietary Trade Name**: Navigated CAPSTONE® Trials, CLYDESDALE® Trials, and CAPSTONE® & CLYDESDALE® Inserter

III. **Common Name**: Stereotaxic Instrument, Implant Trial, Implant Inserter

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

V. **Classification**: Class II

VI. **Product Code**: OLO, MAX

VII. **Product Description:**
The Navigated Trials and Inserter are non-sterile, reusable surgical instruments intended to be used to facilitate implant sizing and placement of Medtronic intervertebral body fusion devices, respectively, during spinal surgery and are specifically designed for use with the StealthStation® System. These navigated interbody devices are used in conjunction with system Trackers, which allows for optical navigation of the surgical instrument, and are also designed for use with the Medtronic CAPSTONE® and CLYDESDALE® Spinal Systems.

VIII. **Indications for Use:**
The Navigated Inserter is intended to be use during implant placement of Medtronic intervertebral body fusion devices during spinal surgery.
The Navigated Trials are intended to be used to facilitate implant size selection of Medtronic intervertebral body fusion devices during spinal surgery.

The navigated instruments 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 a 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)

- NAVIGATED CD HORIZON SOLERA SCREWDRIVERS, TAPS, ILIAC TAPS, LEGACY TAPS (K124004)
- CAPSTONE® SPINAL SYSTEM (K073291, K103731)
- CLYDESDALE® SPINAL SYSTEM (K083026, K112405)

X. Comparison of the Technological Characteristics:

Item	Subject Devices	Predicate Devices
Indications for Use	The Navigated Inserter is intended to be used during implant placement of Medtronic intervertebral body fusion devices during spinal surgery. The Navigated Trials are intended to be used to facilitate implant size selection of Medtronic intervertebral body fusion devices during spinal surgery. The navigated instruments 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 a 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.	***Navigated CD HORIZON® SOLERA™ Screwdrivers, CD HORIZON® SOLERA™ Taps, CD HORIZON® SOLERA™ Iliac Taps and CD HORIZON® LEGACY™ Taps - K124004*** 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.

Item	Subject Devices	Predicate Devices
Intended Use	The Navigated Inserter is intended to be used during implant placement of Medtronic intervertebral body fusion devices during spinal surgery. The Navigated Trials are intended to be used to facilitate implant size selection of Medtronic intervertebral body fusion devices during spinal surgery. The navigated instruments are specifically designed for use with the StealthStation® System.	***CAPSTONE® Spinal System - K073291, K103731*** The trials and inserter are intended to be used during sizing and placement of the CAPSTONE implant devices, respectively. ***CLYDESDALE® Spinal System - K083026, K112405*** The trials and inserter are intended to be used during sizing and placement of the CLYDESDALE implant devices, respectively. ***Navigated CD HORIZON® SOLERA™ Screwdrivers, CD HORIZON® SOLERA™ Taps, CD HORIZON® SOLERA™ Iliac Taps and CD HORIZON® LEGACY™ Taps - K124004*** 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.
Operating Principle (Tracking Method)	Identical	***Navigated CD HORIZON® SOLERA™ Screwdrivers, CD HORIZON® SOLERA™ Taps, CD HORIZON® SOLERA™ Iliac Taps and CD HORIZON® LEGACY™ Taps - K124004*** Optical (infra-red)
Materials – Trials	Identical	***Navigated CD HORIZON® SOLERA™ Screwdrivers, CD HORIZON® SOLERA™ Taps, CD HORIZON® SOLERA™ Iliac Taps and CD HORIZON® LEGACY™ Taps - K124004*** ***CAPSTONE® Spinal System - K073291*** ***CLYDESDALE® Spinal System - K083026*** Material: 17-4 SS

Item	Subject Devices	Predicate Devices
Materials – Inserter	Identical	*CAPSTONE® Spinal System - K103731* 17-4SS, 465 SS, Silicon *CLYDESDALE® Spinal System - K112405* 17-4 SS, Silicon
Materials – Inserter Tracker	Identical	*Navigated CD HORIZON® SOLERA™ Screwdrivers, CD HORIZON® SOLERA™ Taps, CD HORIZON® SOLERA™ Iliac Taps and CD HORIZON® LEGACY™ Taps - K124004* Tracker: 6061 Aluminum, 303 SS
Sterilization Method	Identical	*Navigated CD HORIZON® SOLERA™ Screwdrivers, CD HORIZON® SOLERA™ Taps, CD HORIZON® SOLERA™ Iliac Taps and CD HORIZON® LEGACY™ Taps - K124004* *CAPSTONE® Spinal System - K073291, K103731* *CLYDESDALE® Spinal System - K083026, K112405* Method: 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 instruments accuracy in both 2D and 3D space.
Environmental, Life, and Shipping	Tested navigated instrument functionality after multiple reprocessing cycles (cleaning and sterilization), simulating environmental exposure under expected use conditions and shipping.
Simulated Use	Tested navigated instruments according to the user's needs and intended use.

Test	Description
CAD Model	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.
Implant/Instrument Mating	Verified that the instruments can be attached and mated with the appropriate instrument and/or implant devices according to their intended use.
Spine Tools (Toolcards)	Verified that the Spine Tools package has met the required interface needs of the spine application software.

XII. Conclusions

The Navigated Trials and Inserter 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

August 14, 2013

Regina Holmes
Senior Regulatory Affairs Specialist
Medtronic Navigation, Incorporated
826 Coal Creek Circle
Louisville, Colorado 80027 USA

Re: K131425
Trade/Device Name: Navigated CAPSTONE® Trials, CLYDESDALE® Trials, and CAPSTONE®& CLYDESDALE® Inserter
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, MAX
Dated: June 3, 2013
Received: June 5, 2013

Dear Ms. Holmes:

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

510(k) Number (if known):

Device Name: Navigated CAPSTONE® Trials, CLYDESDALE® Trials, and CAPSTONE® & CLYDESDALE® Inserter

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—Division Sign-Off	Joshua C. Nipper -S
Division of Surgical Devices	
510(k) Number: K131425	