May 17, 2018

Medtronic Sofamor Danek USA, Inc.
Tejas Patel
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K181111
Trade/Device Name: Navigated INFINITY™ Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 26, 2018
Received: April 27, 2018

Dear Tejas Patel:

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.

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.

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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181111

Device Name
Navigated INFINITY™ Instruments

Indications for Use *(Describe)*
Medtronic Navigated Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic 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. Medtronic Navigated Instruments are also compatible with the IPC™ POWEREASE™ 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) Summary**

**April 26, 2018**

**I. Company**: Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone Number: (901) 396-3133

**Contact:** Tejas Patel
Sr. Regulatory Affairs Specialist
Telephone number: (901) 396-3133
Email: tejaskumar.r.patel@medtronic.com

**II. Proprietary Trade Name**: Navigated INFINITY™ Instruments

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

**Common Name**: Navigated Drill Bit

**Classification**: Class II

**Product Code**: OLO

**III. Predicate Device:**

Primary Predicate:

- Navigated INFINITY™ Instruments (K173338, S.E. 01/18/2018)

Additional Predicate:

- Navigated VERTEX SELECT® Instruments (K143628, S.E. 02/12/2015)

These predicates have not been subject to a design-related recall

The following reference devices are also used in this submission:

- INFINITY™ OCT System (K163375, S.E. 08/21/2017)
- IPC® POWEREASE® System (K111520, S.E. 10/26/2011; K123270, S.E. 01/11/2013)
- SteathStation® System (K050438, S.E. 06/02/2005; K170011, S.E. 05/01/2017)
- NavLock™ tracker (K124004, S.E. 03/22/2013)

## IV. Device Description:

The subject Navigated INFINITY™ drill bit is a sterile, single-use instrument that can be operated manually or under power. This instrument is intended to be used when implanting components of the INFINITY™ OCT System. The Navigated INFINITY™ Drill bit is also compatible with the StealthStation® and IPC® POWEREASE® Systems.
*Note:* The subject devices are not intended to support occipital screw placement.

## V. Indications for Use:

Medtronic Navigated Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Medtronic 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. Medtronic Navigated Instruments are also compatible with the IPC® POWEREASE® System.

## VI. Comparison of the Technological Characteristics with the Predicate Device:

The subject drill bit has identical indications, intended use, fundamental scientific technology, materials, dimensions and design features as the Navigated INFINITY™ Instruments recently cleared in K173338 (S.E. 01/18/2018). Identical to the predicate drill bit, the subject drill bit is available in stainless steel. The only technological difference between the subject and predicate Navigated INFINITY™ Instrument is as below:

- The subject navigated drill bit is sterile and single use while the predicate drill bit is non-sterile and single use.

The instrument modifications detailed in this submission have no impact on the technological characteristics of either the existing instruments or the StealthStation® and IPC® POWEREASE® Systems.

## VII. Performance Data:

The following information is provided in support of substantial equivalence.

Sterilization:
The addition of the sterile drill bit does not create a new “worst case” and it was adopted in to the existing product family as detailed in the sterilization rationale provided in this submission since the design, material, manufacturing process, and

manufacturing facilities of the sterile subject devices are equivalent to that of the referenced product family. The sterilization justification supports an SAL of $10^{-6}$.
Based on the information provided in this submission, Medtronic believes that adequate evidence has been provided to show that we have fully validated the sterilization parameters.

## VIII. Conclusions

Based on the sterilization assessment and additional supporting documentation provided in this pre-market notification, the subject Navigated INFINITY™ Instrument demonstrates substantially equivalent to the identified predicate devices.