Medtronic Sofamor Danek, USA Inc
Elizabeth Hamilton
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

August 26, 2019

Re: K191039
Trade/Device Name: Navigated T2 STRATOSPHERE Inserters and Navigated Templates
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 24, 2019
Received: May 28, 2019

Dear Elizabeth Hamilton:

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,

For, Shumaya Ali, MPH
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)*

K191039

Device Name

Navigated T2 Stratosphere Inserters and Navigated Templates

Indications for Use *(Describe)*

The Navigated Disc Preparation Instruments are intended to be used to facilitate a discectomy or boney resection during spinal surgery. The Navigated T2 Stratosphere™ templates are intended to be used to facilitate size selection of vertebral body replacement devices during spinal surgery. The Navigated Capstone™ Trials are intended to be used to facilitate implant size selection of Medtronic intervertebral body fusion devices during spinal surgery. When the Navigated Rotating Shavers are used as trials for Elevate™ Spinal System, they are intended to be used to facilitate implant size selection.

The Navigated Probe is intended to be used during pedicle preparation. The Navigated Inserters are intended to be used for the placement of an implant.

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.

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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K191039

510(K) SUMMARY

April 15, 2019

I. Company: Medtronic Sofamor Danek USA, Inc.
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Memphis, TN 38132
Telephone: (901) 396-3133
Telefax: (901) 346-9738

Contact: Elizabeth Hamilton
Regulatory Affairs Specialist
Telephone number: (901) 399-3395
Email: elizabeth.c.hamilton@medtronic.com

II. **Proprietary Trade Name:** Navigated T2 STRATOSPHERE™ Inserters and Navigated Templates

Common Name: Stereotaxic Instrument, Navigated Instruments
Classification Name: Stereotaxic Instrument (21CFR 882.4560)
Classification: Class II
Product Code: OLO

III. **Predicate Devices:**

- Primary Predicate- Navigated Elevate™ Inserter Disc prep Instruments (K163581, S.E.04/14/2017)
- Predicate 2-T2 STRATOSPHERE™ Expandable Corpectomy System (K173125, S.E. 12/20/2017)
- Predicate 3-Navigated Capstone® Trials, Clydesdale® Trials, Capstone® and Clydesdale® Inserter (K131425, S.E. 08/14/2013)

- Predicate 4-Navigated Disc Prep Instrument and Capstone® Trials (K150231, S.E. 06/16/2015)

IV. Device Description

Medtronic Navigated Reusable Instruments are spine preparation instruments made of high-grade stainless steel. These instruments are specifically designed for use in procedures where the use of stereotactic surgery may be appropriate. Placing Medtronic single-use sterile spheres on each of the tracker passive stems allows a Medtronic computer-assisted surgery system such as the StealthStation™ Image Guidance System to track the instruments in the surgical field. An instrument may incorporate a measuring function which has uses as described on the label and the instrument.

Medtronic Navigated Reusable Instruments are compatible with various Medtronic spinal implant systems.

The purpose of this submission is to seek clearance for Navigated T2 STRATOSPHERE™ Inserters and Navigated Template, compatible with T2 STRATOSPHERE™ Expandable Corpectomy System for lateral and posterior procedures in thoracolumbar cases only.

V. Indications for Use

The Navigated Disc Preparation Instruments are intended to be used to facilitate a discectomy or boney resection during spinal surgery. The Navigated T2 STRATOSPHERE™ templates are intended to be used to facilitate size selection of vertebral body replacement devices during spinal surgery. The Navigated Capstone™ Trials are intended to be used to facilitate implant size selection of Medtronic intervertebral body fusion devices during spinal surgery. When the Navigated Rotating Shavers are used as trials for Elevate™ Spinal System, they are intended to be used to facilitate implant size selection.

The Navigated Probe is intended to be used during pedicle preparation. The Navigated Inserters are intended to be used for the placement of an implant.

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.

VI Substantial Equivalence

Substantial equivalence for the Navigated T2 Stratosphere™ Inserters and Navigated Templates was established in terms of design features, performance testing, materials, sterilization method and indications for use as compared to the predicate devices. The subject devices also have an identical principle of operation and incorporate the same features to enable compatibility with StealthStation® System as the predicate devices. Based on the information provided within this submission, the subject devices have demonstrated to be substantially equivalent to the previously marketed predicate devices.

VII. Performance Data

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. Table 6.0 below summarizes the performance testing completed.

Table 6.0: Description of Performance Testing

Test	Description
Navigation Accuracy Analysis	Confirmed navigated instrument accuracy in both 2D and 3D space.
Anatomical Simulated Use	Confirmed instrument functionality under expected use conditions
Navigated Simulated Use	Confirmed navigation system functionality under expected use conditions

Test	Description
CAD Model Evaluation	Verified that the CAD models are accurately reflected in the application software.
Implant/ Instrument Mating Conditions	Verified that the instruments can be assembled with the appropriate devices according to their intended use.
Spine Tools Package Functional Testing	Verified that the Spine Tools package has met the required interface needs of the spine application software

VIII. **Conclusion**

Based on the test results and additional supporting information provided in this premarket notification, Medtronic believes the subject devices, (Navigated T2 STRATOSPHERE™ Inserters and Navigated Templates) are at least as safe and effective as the legally marketed predicate devices:

- Primary Predicate-Navigated Elevate™ Inserter Disc Prep Instruments (K163581, S.E. 04/14/2017)
- Predicate 2- T2 STRATOSPHERE™ Expandable Corpectomy System (K173125, S.E. 12/20/2017)
- Predicate 3-Navigated Capstone® Trials, Clydesdale® Trials, Capstone® and Clydesdale® Inserter (K131425, S.E. 08/14/2013)
- Predicate 4-Navigated Disc Prep Instrument and Capstone® Trials (K150231, S.E. 06/16/2015)