DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 14, 2017

Medtronic Sofamor Danek USA, Inc
Laveeda Leflore
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K163581
Trade/Device Name: Navigated Elevate Inserter and Navigated Disc Prep Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 19, 2016
Received: December 20, 2016

Dear Laveeda Leflore:

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)*
K163581

Device Name
Navigated ELEVATE™ Inserter and Navigated Disc Prep Instruments.

Indications for Use *(Describe)*
The Navigated Disc Preparation Instruments are intended to be used to facilitate a discectomy 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 and disc preparation during spinal fusion procedures. 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.

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510(k) Summary
December 19, 2016

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

Contact: Laveeda Leflore
Regulatory Affairs Specialist
Telephone: (901) 396-3133
Email: Laveeda.r.leflore@medtronic.com

II. Proprietary Trade Name: Navigated ELEVATE™ Inserter and Navigated Disc Prep Instruments.

Common Name: Stereotaxic Instrument, Navigated Instruments

Classification Name: Stereotaxic Instrument (21 CFR 882.4560)

Classification: Class II

Product Code: OLO

III. Predicate Device:

- Navigated Disc Prep Instruments (K150231, S.E. 06/16/2015) – primary predicate
- Navigated Interbody Trials and Inserter (K131425, S.E. 08/14/2013) – secondary predicate
- ELEVATE™ Spinal System (K142559, S.E. 06/09/2015) – secondary predicate

The predicate devices have not been subject to a design-related recall.

IV. Product Description:

The Navigated ELEVATE™ Inserter and navigated rotating shavers are non-sterile, reusable surgical instruments that are intended to be used to facilitate a discectomy and placement of implants during spinal surgery procedure. The subject devices are designed specifically to be used with ELEVATE™ Spinal System and are also compatible with the StealthStation. These devices are offered in non-sterile form and are reusable.
This subject devices are manufactured from stainless steel and silicone. The case and trays are manufactured from aluminum with either silicone or nylon coated brackets.

V. Indications for Use:

The Navigated Disc Preparation Instruments are intended to be used to facilitate a discectomy 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 and disc preparation during spinal fusion procedures. 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. Comparison of the Technological Characteristics with the Predicate Device:

The subject Navigated ELEVATE™ Inserter is intended to be used for the placement of implants. The subject navigated rotating shavers will have a dual indication. They can be used as shavers to facilitate a discectomy or as trials to facilitate implant size (height) selection of the ELEVATE™ Spinal System implants during a spinal surgery procedure. These instruments are specifically designed for use with the StealthStation® System , which allows for optical navigation of the surgical instruments. These devices have similar designs and uses to the predicate devices and incorporate the same design features to enable navigation capabilities. Like the predicate devices, the subject Navigated ELEVATE™ Inserter and navigated rotating shavers are also made from stainless steel.

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

VII. Performance Data

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

Table 5-1: 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.
Navigation Simulated Use	Confirmed navigation system functionality under expected use conditions.
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.

The Navigated ELEVATE™ Inserter and the rotating shavers will use Tools Package Version 25, which will be compatible with the Synergy Spine 2.1 application on the S7.

VIII. Conclusions

That Navigated ELEVATE™ Inserter and the navigated rotating shavers have been shown through comparison and testing to be substantially equivalent to the identified predicate devices.