April 10, 2019

Boston Endo Surgical Tech
Mr. James Rogers
Director, Regulatory Affairs, Safety and Environment
Division of Lacey Manufacturing Co., LLC
1146 Barnum Ave
Bridgeport, Connecticut 06610

Re: K182662
Trade/Device Name: NAV PAK Needle, NIM NAV PAK Needle
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, PDQ, HAW
Dated: Undated
Received: March 11, 2019

Dear Mr. Rogers:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Matthew C. Krueger -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K182662

Device Name
BE-ST Navigated PAK and Navigated NIM® PAK

Indications for Use *(Describe)*
The BE-ST NAV PAK is indicated for navigated pedicle pilot hole preparation. The BE-ST NAV PAK should only be used with a compatible Medtronic StealthStation® System.

The BE-ST NAV NIM® PAK is indicated for navigated pedicle pilot hole preparation, locating, and identifying nerves during surgery, including spinal nerve roots. The BE-ST NAV NIM® PAK should only be used with compatible Medtronic StealthStation® and Medtronic NIM® Systems.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. **SUBMITTER**

Boston-Endo Surgical Technologies, Division of Lacey Manufacturing Company, LLC
1146 Barnum Avenue
Bridgeport, CT 06610
(203) 336-7453

Prepared by:
James Rogers
Director of Regulatory Affairs, Environment and Safety
Email: jim.rogers@nninc.com
Phone: (203)336-7453

Date Prepared: September 18, 2018

II. **DEVICE**

Name of Device:	BE-ST Navigated PAK Needles
510(k) Number:	K182662
Common Name:	Nerve Stimulator/Locator
Classification Name:	21 CFR 882.4560, Stereotaxic instrument 21 CFR 874.1820, Surgical nerve, stimulator/locator
Review Panel	Neurology
Regulatory Class:	II
Product Code:	OLO, PDQ

III. **IDENTIFICATION OF LEGALLY MARKETED DEVICES (PREDICATE DEVICES)**

Predicate Device

K180542	BE-ST NIM PAK Needle, Blunt, and Pedicle Probe
K170011	Medtronic StealthStation® S8 Spine Software v1.0.0
K050438	Medtronic StealthStation® System Update

IV. **DEVICE DESCRIPTION**

The BE-ST Navigated PAK Needles are single use surgical instruments composed of stainless steel and plastic. They are sterile packaged. The devices are comprised of three main components: the cannula, stylet assembly, and tracker subassembly.

There are two devices in the family: the BE-ST Navigated NIM® PAK Needle and the BE-ST Navigated PAK Needle. The BE-ST Navigated NIM® PAK Needle is an accessory to the Medtronic StealthStation® System and is intended for use as a stimulating accessory to the Medtronic NIM® System. The BE-ST Navigated PAK Needle is an accessory to the Medtronic StealthStation® System.

The only significant differences between the two subject devices are the electrical insulation on the cannula and the connection to the NIM® System. The BE-ST Navigated PAK device has the same basic function and navigational capabilities as the BE-ST Navigated NIM® PAK device but is not an accessory to the Medtronic NIM® system and therefore cannot be used for nerve monitoring.

The Medtronic StealthStation® System and Medtronic NIM® System are not included in the scope of this premarket notification.

V. **INDICATIONS FOR USE**

The BE-ST NAV PAK is indicated for navigated pedicle pilot hole preparation. The BE-ST NAV PAK should only be used with a compatible Medtronic StealthStation® System.

The BE-ST NAV NIM® PAK is indicated for navigated pedicle pilot hole preparation, locating, and identifying nerves during surgery, including spinal nerve roots. The BE-ST NAV NIM® PAK should only be used with compatible Medtronic StealthStation® and Medtronic NIM® Systems.

VI. **COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The BE-ST Navigated NIM® PAK device is based on the predicate Medtronic Navigated NIM-SPINE® PAK Needle. The BE-ST Navigated NIM® PAK device is similar to the BE-ST NIM® PAK device with the addition of a tracker assembly which allows the device to be used with the Medtronic StealthStation® System. The subject device and the BE-ST NIM® PAK device have the same technological features, the same basic geometry, and are manufactured from the same materials, with the exception that the subject device has a tracker assembly which is substantially equivalent to the tracker assembly on the Medtronic predicate device.

The BE-ST Navigated PAK device has the same basic function and navigational capabilities as the BE-ST Navigated NIM® PAK device but does not have neural integrity monitoring capabilities.

The tables below compare the subject and predicate devices.

Comparison of Subject and Predicate Devices				
Characteristic	**Subject Device** BE-ST Navigated NIM® PAK Needle	**Predicate Device** StealthStation System Update	**Predicate** BE-ST NIM® PAK Needle	**Reference Predicate** StealthStation S8 Spine Software v1.0.0
Manufacturer	Boston-Endo Surgical Technologies	Medtronic Navigation	Boston-Endo Surgical Technologies	Medtronic Navigation
510(k)	K182662	K050438	K180542	K170011
Indications for Use	The BE-ST NAV PAK is indicated for navigated pedicle pilot hole preparation. The BE-ST NAV PAK should only be used with a compatible	[…] is indicated for any medical condition in which the use of stereotactic surgery may be appropriate,	[…] is indicated for pedicle pilot hole preparation, locating, and identifying cranial and peripheral motor	[…] is indicated for any medical condition in which the use of stereotactic surgery may be appropriate,

	Medtronic StealthStation® System. The BE-ST NAV NIM® PAK is indicated for navigated pedicle pilot hole preparation, locating, and identifying nerves during surgery, including spinal nerve roots. The BE-ST NAV NIM® PAK should only be used with compatible Medtronic StealthStation® and Medtronic NIM® Systems	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.	nerves during surgery, including spinal nerve roots.	and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to images of the anatomy.

Technological Comparison of Subject and Predicate Devices			
Characteristic	BE-ST Navigated NIM® PAK Needle	Medtronic Navigated NIM-SPINE® PAK Needle	BE-ST NIM® PAK Needle
Manufacturer	Boston-Endo Surgical Technologies	Medtronic Navigation	Boston-Endo Surgical Technologies
Accessory to Medtronic StealthStation® System	Yes	Yes	No
Accessory to Medtronic NIM® System	Yes	Yes	Yes
Technological features	Same as predicate	Same as subject	Same as subject with exception of tracker assembly used for navigation
Construction Materials	Stainless steel – stylet, cannula, self-tapping screws, and posts Polymer – stylet handle, cannula hub, and tracker assembly Polyester – cannula electrical insulation	Stainless steel – stylet, cannula, self-tapping screw, and posts Polymer – stylet handle, locking ring, cannula hub, and tracker assembly Nylon – cannula electrical insulation	Stainless steel – stylet and cannula Polymer – stylet handle, cannula hub Polyester – cannula electrical insulation
Electrical insulation	On all cannula surfaces not intended to provide electrical contact with the patient.	On all cannula surfaces not intended to provide electrical contact with the patient.	On all cannula surfaces not intended to provide electrical contact with the patient.
Distal tip	Same as predicate	Same as subject	Same as subject
Stylet handle/cannula Hub connection	Overmolded stylet handle that locks to overmolded cannula hub	Removable handle with a locking ring the locks the handle to the cannula and/or stylet.	Overmolded stylet handle that locks to overmolded cannula hub
Biocompatible	Yes	Yes	Yes

Single Use	Yes	Yes	Yes
Sterilization Method(s)	Sterile (ETO)	Sterile (ETO)	Sterile (gamma)
Environment of Use	Intraoperative	Intraoperative	Intraoperative
Duration of Use	< 24 hours	< 24 hours	< 24 hours

The subject device was shown to be substantially equivalent to the predicate devices through dimensional and functional testing.

VII. **PERFORMANCE DATA**

The subject device conforms to the following standards:

- ANSI/AAMI ST72:2011/(R) 2016, Bacterial endotoxins: Test methods, routine monitoring, and alternatives to batch testing.
- ASTM A313, Standard Specification for Stainless Steel Spring Wire (2017)
- ASTM A269, Standard Specification for Seamless and Welded Austenitic Stainless Steel Tubing (2015a)
- ISO 10993-4:2017, Biological Evaluation of Medical Devices: Tests for interactions with blood
- ISO 10993-5:2009, Biological Evaluation of Medical Devices: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010, Biological Evaluation of Medical Devices: Tests for irritation and sensitization.
- ISO 10993-11:2017, Biological Evaluation of Medical Devices: Tests for systemic toxicity.
- ISO 11135:2014, Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices.
- ISO 11607-1:2006, Packaging for terminally sterilized medical devices: Requirements for materials, sterile barrier systems and packaging systems.
- ISO 11607-2:2006, Packaging for terminally sterilized medical devices: Validation requirements for forming, sealing and assembly processes.
- ISO 11737-1:2018, Sterilization of medical devices - Microbiological methods: Determination of a population of microorganisms on products.
- ISO 11737-2:2009, Sterilization of medical devices - Microbiological methods: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
- USP <85>, Bacterial Endotoxins Test.
- USP <151>, Rabbit Pyrogen Test
- USP <161>, Medical Devices: Bacterial Endotoxin and Pyrogen Tests

The table below summarizes the testing which was performed on the subject devices to show substantial equivalence to the predicate devices.

Test	Test Method Summary	Results
Functional use and reliability testing	The following functional use tests were performed on the subject devices and the predicate devices. For all tests, the results were compared to verify substantial equivalence. • Impact testing into simulated bone with snap lock testing of cannula and stylet handles • Hipot testing, continuity testing, and visual analysis following impact testing • Instron insertion and removal testing in simulated bone	Devices passed all functional use and reliability testing
Biocompatibility testing	Biocompatibility testing conducted on ETO sterilized, finished devices per ISO 10993. • Cytotoxicity: MEM Elution testing • Sensitization: Magnusson-Kligman Method • Irritation: Intracutaneous Toxicity • Systemic Toxicity: Systemic Injection Test • Material Mediated Pyrogen test: Rabbit Pyrogen Test • Hemolysis: Extract method test	Devices passed biocompatibility testing
ETO sterilization validation	ETO sterilization validation per ISO 11135. Validation achieved a SAL of 10^{-6}. The residual ETO limit for the devices is <4mg/device EO and <9mg/device ECH per ISO 10993-7. Following validation, routine bioburden testing will be performed on the devices.	ETO sterilization validation completed successfully
Packaging durability testing	Ship testing on final finished, packaged, sterilized, devices. The ship testing was comprised of the following steps: • ISTA 1C Test o Environmental pre-conditioning o Compression test o Vibration test – fixed vibration o Vibration test – random vibration o Drop testing – corner, edge, and face drop • Visual analysis of outer packaging, inner and outer blisters, and device • Inner and outer blister seal integrity testing via dye injection	Devices passed ship testing
Packaging process validation	Packaging heat sealing process validation • Heat sealing OQ o Seal width verification o Visual inspection o Seal strength process capability analysis • Heat sealing PQ conducted at nominal heat sealing parameters	Packaging process validation completed successfully

Age testing (device and packaging)	36 month accelerated aging on packaging and devices followed by functional use testing and packaging integrity testing. • Accelerated aging to 36 months • Device o Functional use testing of devices including impact testing o Visual, Hipot, and conductivity verification is conducted before and after impact testing. o Snap lock testing of cannula and stylet handles • Packaging o Seal integrity testing using dye penetration method o Seal strength testing	Devices and packaging passed age testing.
Surface area validation	Performed dimensional analysis	Surface area found to be substantially equivalent.
Device navigational accuracy and compatibility with Medtronic StealthStation® System	Accuracy and compatibility testing with Medtronic StealthStation® System. • Testing conducted by Medtronic • Devices registered by the StealthStation® System • Devices tested to the accuracy criteria for the StealthStation® System	Devices passed accuracy testing, meeting the confidence/reliability tolerance interval requirement.

VIII. **CONCLUSIONS**

The Navigated NIM® PAK Needle and the Navigated PAK Needle are intended for use as accessories to the Medtronic StealthStation® System. The Navigated NIM® PAK Needle is additionally intended for use as a stimulating accessory to the Medtronic NIM® System.

As confirmed through bench testing; the subject devices have the same safety and effectiveness profile as the predicate devices.