August 22, 2018

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

Re: K180542
Trade/Device Name: BE-ST NIM® PAK Needle, Blunt, and Pedicle Probe
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: July 26, 2018
Received: July 26, 2018

Dear James 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,

Jay R. Gupta -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)*
K180542

Device Name
BE-ST NIM® PAK Needle, Blunt, and Pedicle Probe

Indications for Use *(Describe)*
The BE-ST NIM® PAK Needle, Blunt, and Pedicle Probe are indicated for pedicle pilot hole preparation, locating, and identifying cranial and peripheral motor nerves during surgery, including spinal nerve roots.

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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"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: July 17, 2018

II. DEVICE

Name of Device:	BE-ST NIM® PAK Needle, Blunt, and Pedicle Probe
Common Name:	Nerve Stimulator/Locator
Classification Name:	21 CFR 874.1820, Surgical nerve, stimulator/locator
Review Panel:	Neurology
Regulatory Class:	II
Product Code:	PDQ

III. PREDICATE DEVICE

Medtronic Stimulation/Dissection Instruments, Ball-tip probes, K031003
Medtronic NIM Spine, K031510

No reference devices.

IV. DEVICE DESCRIPTION

The BE-ST NIM® PAK Needle, Blunt, and Pedicle Probe are single use devices composed of stainless steel and plastic and are sterile packaged. The devices are comprised of two main components: the cannula and stylet assembly. Also, in the package are two monopolar cables: a subdermal needle electrode and a connecting cable. The NIM® PAK devices are available in standard "NIM® PAK" or longer "NIM® XPAK" configurations with 3 different types of tips: bevel, trocar or blunt. The blunt tips are only offered for the NIM® XPAK. In addition, there are three (3) NIM Pedicle Probes in lumbar, straight, and thoracic configurations.

The BE-ST NIM® product family has a total of four (4) pedicle access needle configurations, three (3) pedicle probe configurations, and one (1) blunt configuration. All configurations are packaged with two (2) accessory monopolar cables. One cable is used to ground the patient and the other cable is used to connect the device to a Medtronic Neural Integrity Monitor (NIM®).

The connection to the NIM® allows the subject device to provide stimulation to nerves. Refer to K031510 for NIM® submission.

The BE-ST NIM® PAK Needle, Blunt, and Pedicle Probe are intended for use as a stimulating accessory to the Medtronic NIM® System.

V. INDICATIONS FOR USE

The BE-ST NIM® PAK Needle, Blunt, and Pedicle Probe are indicated for pedicle pilot hole preparation, locating, and identifying cranial and peripheral motor nerves during surgery, including spinal nerve roots.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The predicate devices and the subject device are the similar. The same technology and sterilization methods and similar materials are used to manufacture the subject devices. There are no technological differences between the two systems. The table below compares the subject and predicate devices.

Characteristic	**Subject Device** BE-ST NIM® PAK Needle, Blunt, and Pedicle Probe	**Predicate Device** Stimulation/Dissection Instruments Medtronic NIM® Spine
Manufacturer	Boston-Endo Surgical Technologies	Medtronic
510(k)	Pending (K180542)	K031003, K031510
Indications for Use	[…] indicated for pedicle pilot hole formation, locating, and identifying cranial and peripheral motor nerves during surgery, including spinal nerve roots	[…] indicated for locating and identifying cranial and peripheral motor nerves during surgery, including spinal nerve roots
Technological features	Similar to predicate	Similar to subject
Polymer handle and hub	Yes	Yes
Stainless steel construction	Yes	Yes
Electrical insulation	On all surfaces not intended to provide electrical contact with the patient.	On all surfaces not intended to provide electrical contact with the patient.
Distal stainless steel patient contact surface	Yes	Yes
Device geometry	Substantially equivalent geometry to predicate	Substantially equivalent geometry to subject
Proximal stimulator connector	Yes	Yes
Biocompatible	Yes	Yes
Sterile, single use only	Yes	Yes
IEC 60601-1 passing results	Yes	Yes

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

The main difference between the subject and predicate devices is the design of the handle. The subject devices also have an improved locking mechanism which allows the user to lock the stylet handle to the cannula with a quarter turn bayonet-type locking mechanism. In addition, an audible "click" provides the user with assurance that the handle is locked into place.

Additionally, the electrical insulation was changed from nylon to polyester. The polyester insulation material passed biocompatibility testing pursuant to ISO 10993-4, 10993-5, 10993-10, and 10993-11.

VII. PERFORMANCE DATA

The subject device conforms to the following standards:

- ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials (2017)
- ASTM F899-1, Standard specification for wrought stainless steel for surgical instruments (Version 11) (2009).
- IEC 60601-1:2005 Medical Electrical Equipment - Part 1: General requirements for safety, Amendment 1, Amendment 2.
- ISO 10993-4:2017, Biological Evaluation of Medical Devices: Tests for interactions with blood
- ISO 10993-5:, Biological Evaluation of Medical Devices: Tests for in vitro cytotoxicity (1999)
- ISO 10993-10, Biological Evaluation of Medical Devices: Tests for irritation and sensitization.
- ISO 10993-11, Biological Evaluation of Medical Devices: Tests for systemic toxicity
- ANSI/AAMI ST72:2011/(R) 2016, Bacterial endotoxins: Test methods, routine monitoring, and alternatives to batch testing.
- USP <161>, Medical Devices: Bacterial Endotoxin and Pyrogen Tests.
- USP <151>, Pyrogen Test.
- USP <85>, Bacterial Endotoxins Test.
- ISO 11737-1, Sterilization of medical devices - Microbiological methods: Determination of a population of microorganisms on products (2006).
- ISO 11737-2, Sterilization of medical devices - Microbiological methods: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (2000).
- ISO 11607-1, Packaging for terminally sterilized medical devices: Requirements for materials, sterile barrier systems and packaging systems (2006).
- ISO 11607-2, Packaging for terminally sterilized medical devices: Validation requirements for forming, sealing and assembly processes (2006).

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	All functional use and reliability testing passed. Substantial equivalence has been shown.
Mechanical and electrical safety testing	Testing was performed on the subject devices in accordance with IEC 60601-1: 2005 Ed. 3. The following tests were performed: Dielectric strength test, mechanical strength, push test, drop test, mold stress relief test.	Subject devices passed electrical safety testing, demonstrating that the devices meet the requirements for the subject device.
Biocompatibility testing	Biocompatibility testing conducted on gamma 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	All devices passed biocompatibility testing
Sterility	The devices have been gamma sterilization validated in accordance with ISO 11137 using the VD_{max}^{25} method of validation.	Sterility validation met requirements of ISO 11137.
Transit testing	Transit testing was adopted from the PAK family of devices. The subject devices utilize the same packaging and have the same basic size, shape, and weight as the PAK devices. • ISTA 1C Test: Environmental pre-conditioning, Compression test, Vibration test – fixed vibration, Vibration test – random vibration, 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	Packaging met transit testing requirements; transit testing adoption from PAK family of devices

Sterile barrier heat sealing	Packaging heat sealing was adopted from the PAK family of devices. The subject devices utilize the same packaging and have the same basic size, shape, and weight as the PAK devices.	Heat sealing process successfully validated; packaging process adoption from the PAK family of devices.
Shelf life testing (device)	36 month accelerated aging of packaged devices followed by functional use testing.	Age testing in progress.
Shelf life testing (packaging)	36 month accelerated aging of packaging followed by seal strength testing, package conditioning, and seal integrity testing.	36 month shelf life successfully validated; packaging shelf life adoption from the PAK family of devices.

BE-ST conducted a cadaver lab test where the subject devices, connected to the Medtronic NIM® System, were successfully used to create a pilot hole which was successfully tapped and fitted with a pedicle screw. The results of the lab validated that the device design outputs met the user needs (design inputs).

Pyrogen status for general medical devices was evaluated using the LAL test. Testing to monitor pyrogens will be performed periodically.

VIII. CONCLUSIONS

The subject device is only intended for use with the Medtronic NIM® System. As confirmed through bench, clinical, and lab testing; the subject device has the same safety and effectiveness profile as the predicate device.