DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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February 19, 2015

NDI Medical, LLC
c/o Mr. Robert Rogers
Director, Regulatory Affairs and Quality Systems
22901 Millcreek Blvd., Suite 110
Cleveland, OH 44122

Re: K150005
Trade/Device Name: Checkpoint® Head & Neck
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: January 19, 2015
Received: January 20, 2015

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. 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" (21CFR 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 yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K150005

Device Name: Checkpoint® Head & Neck

Indications for Use:

The Checkpoint® Head & Neck is a single-use device intended to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.

Prescription Use __**X**__ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

for the

Checkpoint® Head & Neck

1. SPONSOR/APPLICANT

NDI Medical, LLC
22901 Millcreek Boulevard, Suite 110
Cleveland, OH 44122

Contact Person: Robert Rogers, Director, Regulatory Affairs and Quality Systems
Telephone: 216-378-2163
Fax: 216-378-9116

Date Prepared: December 26, 2014

2. DEVICE NAME

Trade/Proprietary Name:	Checkpoint® Checkpoint Head & Neck
Common/Usual Name:	Surgical Nerve Stimulator/Locator
Classification Name:	Surgical Nerve Stimulator/Locator (21 CFR 874.1820, Product Code: ETN)

3. PREDICATE DEVICE

K092292 - Checkpoint® Surgical Nerve Stimulator/Locator

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The Checkpoint Head & Neck is a small handheld device used by a surgeon to deliver electrical stimulation intraoperatively to locate and identify nerves, and to test nerve integrity and muscle excitability. These are sterile disposable devices designed to be simple to use with one-handed control.

The device uses a stimulating probe that is attached to the distal end and a cable attached to a needle return electrode on the proximal end. The microcontroller in the device includes embedded firmware that

controls the function of the Stimulator. The firmware cannot be modified by the user. The stimulator is powered by internal batteries that are not user replaceable, thereby minimizing the potential for re-use.

Both the modified Checkpoint and the Checkpoint Head & Neck are available for prescription use only.

This functionality is useful in many surgical procedures such as locating and identifying nerves so as to protect them from inadvertent damage. It can also enhance nerve exploration and repair and facilitate assessment of nerve integrity by delivering nerve stimulation at the beginning and end of a procedure to evaluate nerve and muscle excitability following a particular surgical intervention.

The materials of the modified Checkpoint and Checkpoint Head & Neck that are in direct tissue contact are unchanged; stainless steel (304) and Altera medical grade polyolefin tubing comprise the probe. The material composition of the housing of the both devices, which may come into incidental contact with exposed issues, is also unchanged. Both are molded of a medical grade of ABS plastic resin. The nose-cone section is a flexible elastomer overmold. The light ring is made of a medical grade thermoplastic, which also includes a medical grade colorant. The wire connecting the needle electrode to the housing is insulated with medical grade PVC.

5. INTENDED USE

The Checkpoint Head & Neck is a single-use device intended to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.

Both the subject device and the predicate devices have the same intended use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both devices use a stimulating probe that is attached to the proximal end and a cable attached to a needle return electrode on the distal end.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Hand-held, Sterile, Single-use, disposable
- Integral stimulus probe
- Monopolar stimulation
- Current and Patient Leakage Current
- Battery powered
- Software/Firmware/Microprocessor Control
- LED based visual indicator flashes yellow to notify the user that the selected stimulus is being delivered to the Probe
- LED based visual indicator flashes red to notify the user that the requested stimulus current is not being delivered to the Probe
- LED based visual Indicator also identifies device off and device in standby
- Weight, dimensions, and housing materials and construction

The following technological differences exist between the subject and predicate devices:

- Automatic shut-off time interval – the subject device will shut off after 4 hours in contrast to the predicate device which shuts off after 7 hours

- Pulse duration settings – the subject device has fixed pulse settings while the predicate device has variable settings
- Structure – the slide control for pulse settings has been removed

7. PERFORMANCE TESTING

Testing of this device includes biocompatibility testing, electrical testing (safety and electromagnetic compatibility), as well as design verification and validation testing.

8. CONCLUSIONS

The modified Checkpoint and Checkpoint Head & Neck stimulators are identical in their intended use, principles of operation, fundamental design and technology, and operation. The differences between them are in the narrower range of stimulus parameters and associated product and labeling changes, as well as in construction changes. The Checkpoint Head & Neck is substantially equivalent to the modified Checkpoint device.