K092292

510(k) Summary
for the
NDI Medical Checkpoint®

1. SPONSOR/APPLICANT

NDI Medical
22901 Millcreek Boulevard, Suite 110
Cleveland, OH 44122
216-378-9106

OCT 2 8 2009

Contact Person: Julie Grill, VP, Regulatory Affairs
Telephone: 919-968-4690

Date Prepared: July 29, 2009

2. Device Name

Trade/Proprietary Name: Checkpoint®
Common/Usual Name: Surgical Nerve Stimulator/Locator
Classification Name: Surgical Nerve Stimulator/Locator

3. PREDICATE DEVICE

K061365 - Checkpoint Surgical Nerve Stimulator/Locator

4. DEVICE DESCRIPTION

The Checkpoint® is a small handheld device used by a surgeon to deliver electrical stimulation intraoperatively to test nerve integrity and muscle excitability. This is a sterile disposable device designed to be simple to use with one-handed control.

5. INTENDED USE

The Checkpoint® is a single-use sterile 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The determination of substantial equivalence of the modified Checkpoint and original Checkpoint® devices was based on equivalence of intended use, indications for use, operational characteristics, and fundamental technological characteristics.

Feature/Characteristic	Checkpoint K061365	Modified Checkpoint
The Checkpoint is a single-use, sterile 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.	Yes	Yes
Hand-held	Yes	Yes
Disposable	Yes	Yes
Integral stimulus probe	Yes	Yes
Monopolar stimulation	Yes	Yes
Battery Powered	Yes	Yes
Regulated Current	Yes	Yes
Biphasic rectangular waveform with no net DC current	Yes	Yes
Separate Stimulus Amplitude and Pulse Duration controls	Yes	Yes

7. PERFORMANCE TESTING

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NDI Medical, LLC
c/o Ms. Julie Grill
VP, Regulatory Affairs and Quality Systems
22901 Millcreek Blvd.
Suite 110
Cleveland, OH 44122

OCT 28 2009

Re: K092292
Trade/Device Name: Checkpoint, Model 9014
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: II
Product Code: ETN
Dated: September 24, 2009
Received: September 25, 2009

Dear Ms. Grill:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K092292

Device Name: Checkpoint®

Indications for Use:

The Checkpoint® is a single-use sterile 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. The Checkpoint is available for prescription use only.

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)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092292