510(k) Summary
for the
NDI Medical Checkpoint®

1. **SPONSOR/APPLICANT**
   
   NDI Medical
   22901 Millcreek Boulevard, Suite 110
   Cleveland, OH 44122
   216-378-9106

   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.

<table>
<thead>
<tr>
<th>Feature/Characteristic</th>
<th>Checkpoint K061365</th>
<th>Modified Checkpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Hand-held</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Disposable</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Integral stimulus probe</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Monopolar stimulation</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Battery Powered</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Regulated Current</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Biphasic rectangular waveform with no net DC current</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Separate Stimulus Amplitude and Pulse Duration controls</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

7. PERFORMANCE TESTING

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

(Please do not write below this line—continue on another page if 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