K061365

510(k) Summary
for the
NDI Medical Checkpoint™

JUL 12 2006

1. SPONSOR/APPLICANT

NDI Medical
One Chagrin Highlands
2000 Auburn Drive
Suite 320
Cleveland, OH 44122
216-378-9106

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

Date Prepared: May 15, 2006

2. Device Name

Trade/Proprietary Name:	Checkpoint™ with Accustim Technology
Common/Usual Name:	Surgical Nerve Stimulator/Locator
Classification Name:	Surgical Nerve Stimulator/Locator

3. PREDICATE DEVICES

- Medtronic Xomed Vari-Stim III (pre-amendment device) Medtronic Xomed (originally Concept Medical)
- Aaron Neuro-Pulse (K905045), Aaron Medical
- Xomed Nerve Integrity Monitor Response 2.0 and NIM2-XL (K934426) Medtronic Xomed-Treace, Inc.

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 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 Checkpoint™ and cited predicate devices was based on equivalence of intended use, indications for use, operational characteristics, and fundamental technological characteristics.

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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NDI Medical
c/o Julie Grill
Vice President, Regulatory Affairs
One Chagrin Highlands
2000 Auburn Drive, Suite 320
Cleveland, OH 44122

JUL 12 2006

Re: K061365
Trade/Device Name: NDI Medical Checkpoint™
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: June 30, 2006
Received: July 3, 2006

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): To be assigned K061365

Device Name: Checkpoint™

Indications for Use:

The Checkpoint™ 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Ear, Nose and Throat Devises

510(k) Number K061365

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