

K070109

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**510(k) Summary  
for  
NeuroMetrix ADVANCE™**

**APR 25 2008**

**1. SPONSOR**

NeuroMetrix, Inc.  
62 Fourth Avenue  
Waltham, MA 02451

Contact Person: Rainer Maas  
Telephone: (781) 314-2781  
Date Prepared: April 25, 2008

**2. DEVICE NAME**

Proprietary Name: ADVANCE  
Common/Usual Name: 2-channel electromyograph for nerve conduction studies and  
needle electromyography  
Classification Name: 890.1375 IKN Diagnostic Electromyograph  
882.1550 JXE Nerve Conduction Velocity  
Measurement Device

**3. PREDICATE DEVICES**

- Dantec Keypoint® (K944547)
- NeuroMetrix NC-stat® (K060584, K041320, K013459)

**4. INTENDED USE**

NeuroMetrix ADVANCE is intended to perform nerve conduction studies and needle electromyography procedures. As such, NeuroMetrix ADVANCE is intended to measure neuromuscular signals that are useful as an aid in diagnosing and evaluating patients suspected of having focal or systemic neuropathies. If the elective needle EMG module is used, then the device is also intended to measure signals that are useful as an aid in evaluating disorders of muscles.

This device must be used in the context of other patient information. Its output must be reviewed and interpreted by a physician who will exercise professional judgment when using this information.

## 5. DEVICE DESCRIPTION

The NeuroMetrix ADVANCE System consists of the following components:

5.1 A Device that features a high-resolution touch-screen display panel with a stylus. The Device has a cable that connects to disposable surface electrodes for performance of nerve conduction studies. The Device communicates via Bluetooth with an accessory EMG Module that connects to electromyography needles for performance of invasive needle electromyography studies. The Device amplifies, digitizes and stores nerve and muscle signals. It delivers electrical stimuli through the electrodes for nerve conduction studies. Nerve conduction and needle electromyography waveforms are displayed in real time. The Device reports standard nerve conduction parameters based on operator or computer assigned waveform cursors. Nerve conduction parameters include motor and sensory latency, motor and sensory conduction velocity, F-wave response parameters, A-waves, motor and sensory amplitude and waveform configuration. The Device may optionally upload stored data to the Communications Hub. The Device is powered by a rechargeable battery pack or by three standard AA alkaline batteries.

The Device may be used with the Proximal Stimulation Adapter, which is an accessory used to extend the physical reach of the Device connector and thereby enables proximal nerve stimulation.

5.2 A Charger that also houses the Device. In addition to charging the Device, it features a spare battery pack charger along with three LED indicators and is powered by an AC adapter

5.4 A Communications Hub that receives optional data uploads from the Device via Bluetooth and transmits the data to the onCall Information System for data storage and direct transference of acquired waveforms and nerve conduction parameters to a remote printer without further post-processing or data analysis. The Communications Hub is powered by an AC adapter.

5.5 A Needle EMG Module that enables invasive needle electromyography recordings. The Needle EMG Module connects to standard concentric sterile EMG needles and a surface electrode. With the needle inserted into a muscle of interest, the Needle EMG Module amplifies myoelectrical signals and transmits them to the Device via Bluetooth where they are continuously displayed. The electromyographic signals are also concurrently played through an integrated loud-speaker.

- 5.6 A Cart that houses and charges the Device and its accessories to facilitate patient testing.

**6. BASIS FOR SUBSTANTIAL EQUIVALENCE**

The NeuroMetrix ADVANCE System, which is the subject of this 510(k) Premarket Notification, is substantially equivalent to the predicate Dantec Keypoint (K944547) and the NeuroMetrix NC-stat as previously cleared for marketing in K060584, K041320, and K013459. The purpose of this 510(k) is to describe the NeuroMetrix ADVANCE System including:

- 6.1 High resolution LCD touch screen for real-time display of nerve conduction waveforms and response parameters and needle electromyography signals.
- 6.2 Ability of the physician to perform real-time assignment of motor, F-wave and sensory nerve conduction waveform cursors with the supplied stylus.
- 6.3 Module for performance of invasive needle electromyography procedures.
- 6.4 Bluetooth wireless technology communication capability.
- 6.5 Enhanced algorithms for analysis of F-wave responses.

None of the features of the NeuroMetrix ADVANCE System have altered the basic performance, operation, or intended use of the device as compared with the predicate Dantec Keypoint (K944547). The ADVANCE System expands on the performance and operation of the NC-stat (K060584, K041320, K013459) by interfacing with individual electrodes, providing real-time waveform display, allowing manual waveform cursor assignment, and supporting invasive needle electromyography testing. ADVANCE improves on both predicate devices by incorporating an integrated high-resolution LCD touch screen, Bluetooth wireless transmission technology, and enhanced F-wave response analysis algorithms.

As demonstrated by a comparison of technical specifications, inclusion of validation reports, and provision of performance and clinical data in this 510(k), the NeuroMetrix ADVANCE System is substantially equivalent to the Dantec Keypoint (K944547) and the NeuroMetrix NC-stat (K060584, K041320, K013459).

ADVANCE System reliability was demonstrated by performance data submitted in this 510(k). The reproducibility of nerve conduction parameters derived from computer based data acquisition and waveform cursor assignments was assessed in 15 subjects; 14 of whom had symptoms of potential neuropathies. The median, ulnar, deep peroneal, posterior tibial, and sural nerves were evaluated bilaterally in each subject at two test

sessions 3-7 days apart; two tests were performed within 10 minutes at each session. All the nerve conduction parameters listed in Section 5.1 above were measured. Variance components analyses were performed on all parameters via a nested variance model. The two outcome measures were “between test” reliability and “between session and test” reliability. The “between test” reliability quantified the short-term variation in device measurements and therefore represented the neurophysiological variability inherent in nerve conduction testing and the variability attributable to the ADVANCE System in the absence of operator intervention. The “between session and test reliability” quantified the variation between tests performed 3-7 days apart with distinct electrode placements. In this instance, sources of variability independent of the ADVANCE System were present and included differences in electrode placement and inter-session physiological changes.

A total of 6,659 nerve conduction parameters were measured and analyzed. The results quantified ADVANCE System reliability as the “between test” coefficient of variation and the “between session and test” coefficient of variation. These performance metrics were benchmarked against three large studies of nerve conduction reliability in which the measurements were performed by clinical neurophysiology specialists with oversight by a central review laboratory (Bril et al. 1998, Kohara et al. 2000, Bird et al. 2006). The reliability of motor and sensory latencies, conduction velocities, F-wave latencies, and motor and sensory amplitudes were comparable to the benchmark studies. Furthermore, the ranking of reliability, whereby F-wave latencies had the best performance and amplitudes the worst, was also consistent with the benchmark studies.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NeuroMetrix, Incorporated  
% Mr. Rainer N. Maas  
Director, QA/RA  
62 Fourth Avenue  
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APR 25 2008

Re: K070109  
Trade Device Name: ADVANCE  
Regulation Number: 21 CFR 882.1550  
Regulation Name: Nerve conduction velocity measurement device.  
Regulatory Class: Class II  
Product Code: JXE, IKN  
Dated: March 7, 2008  
Received: March 10, 2008

Dear Mr.Maas:

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.

Page 2 –Mr. Rainer N. Maas

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

