K060584

510(k) Summary
for
NeuroMetrix NC-stat

JUL 31 2006

1. SPONSOR

NeuroMetrix, Inc.
62 Fourth Avenue
Waltham, MA 02451

Contact Person: Rainer Maas
Telephone: (781) 314-2781

Date Prepared: July 26, 2006

2. DEVICE NAME

Proprietary Name: NC-stat
Common/Usual Name: Nerve Conduction Testing System
Classification Name: Nerve Conduction Velocity Measuring Device

3. PREDICATE DEVICES

- NC-stat (K982359, K000565, K003508, K013459 and K041320)
- TECA TD-10/TD-20 (K802637)

4. INTENDED USE

The NeuroMetrix NC-stat is intended to stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.

5. DEVICE DESCRIPTION

The NC-stat system consists of the following four components:

5.1 An instrument that contains the electronic circuitry and software required to control a nerve conduction study, including determination of the supramaximal stimulus intensity, acquisition and analysis of motor and

sensory waveforms, and display of latency/conduction velocity, amplitude and response configuration parameters. The instrument saves patient and study data for optional transmission to a docking station for real-time hard copy report generation. The instrument displays nerve conduction data in real-time on the LCD readout, including the distal motor latency (DML), Compound Muscle Action Potential (CMAP) amplitude, CMAP duration, CMAP area, motor conduction velocity (CV), F-wave latency, distal sensory latency (DSL), the Sensory Nerve Action Potential (SNAP) amplitude, SNAP duration, sensory CV, limb indicator (left or right), low battery indicator, the memory slot being used to store the test data, and user messages (menu selections, sensor serial numbers, device status, operator instructions, and error conditions).

5.2 A stationary docking station is used to download the test data from the instrument via an infra-red communication link to the onCall Information System via an analog phone line. The docking station is non-transportable and connected to both a power outlet and an analog phone line.

5.3 Single-use, disposable biosensors are available for the median motor, ulnar motor, median motor & sensory, ulnar motor & sensory, deep peroneal, posterior tibial, and sural nerves. The biosensors contain electrodes for nerve stimulation, response detection, and skin surface temperature measurement.

5.4 The onCall Information System for automatic generation of the hardcopy patient test report, which includes test results (DML, Compound Muscle Action Potential – CMAP- amplitude, DSL, SNAP amplitude, conduction velocity, F-wave latency, and associated response waveforms) and comparison of patient results to normal ranges. Reports are sent to the user by facsimile or e-mail.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The NC-stat that is the subject of this 510(k) Premarket Notification is substantially equivalent to the NC-stat as previously cleared for marketing and to the TECA TD-10/TD-20 EMG and nerve conduction velocity measurement device. The purpose of this 510(k) is to describe changes made to the NC-stat, including:

6.1 Addition of the modified median motor-sensory biosensor for use in diagnosing neuropathies affecting the median motor-sensory nerves.

6.2 Modifications to the labeling.

None of the changes to the NC-stat have altered the intended use of the device, the basic device design or the device operation. Clinical data submitted in the 510(k) demonstrates that nerve conduction measurements obtained using the NC-stat are comparable to those obtained using conventional nerve conduction measurement equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2006

NeuroMetrix, Inc.
% Rainer Maas
Director, Quality Assurance and Regulatory
Affairs Associate
62 Fourth Avenue
Waltham, Massachusetts 02451

Re: K060584
Trade/Device Name: NC-stat
Regulation Number: 21 CFR 882.1550
Regulation Name: Nerve conduction velocity measurement device
Regulatory Class: II
Product Code: JXE, IKN
Dated: July 5, 2006
Received: July 6, 2006

Dear Rainer 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.
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,

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

Enclosure

Intended Use

510(k) Number (if known): K060584

Device Name: NC-stat

Intended Use:

The NeuroMetrix NC-stat is intended to stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060584