K982359

OCT 2 1998

510(k) Summary
for
NC-stat

1. SPONSOR

NeuroMetrix, Inc.
One Memorial Drive
Cambridge, MA 02142

Contact Person: Shai N. Gozani, M.D., Ph.D.
CEO
Telephone: 617-225-7774

Date Prepared: September 28, 1998

2. DEVICE NAME

Proprietary Name: NC-stat
Common/Usual Name: Nerve Conduction Monitoring System
Classification Name: Nerve Conduction Velocity Measurement Device

3. PREDICATE DEVICES

The NeuroMetrix NC-stat is substantially equivalent to the following devices:

- Neurotron Neurometer Premarket Notification K853608
- TECA TD-10/TD-20 EMG Premarket Notification K802637

4. DEVICE DESCRIPTION

The NC-stat consists of a hand-held, battery-operated monitor and a disposable sensor. The NC-stat measures two median nerve electrophysiological parameters, the distal motor latency (DML) and the median F-wave latency (F-LAT). The DML is the interval, in milliseconds, between the onset of the stimulus and the onset of the resultant compound muscle action potential (CMAP) in the thenar muscles. The F-LAT is the median interval, in milliseconds, between the onset of the stimulus and the onset of a CMAP in the thenar muscle resulting from

antidromic activation of the motor neurons in the spinal cord. The primary and secondary functions of the NC-stat are controlled by software routines. The primary function of the NC-stat software is to carry out nerve conduction measurements. Secondary functions of the software include displaying previously acquired measurement data, communicating stored data to an external target such as a printer and operating hardware diagnostics when the device is initially powered on.

The single-use disposable sensor, containing a proprietary electrode array, is placed on the patient's wrist in alignment with the distal most wrist crease and connected to the monitor. The monitor non-invasively stimulates the patient's median nerve and detects the subsequent CMAP as an electrical potential on the skin, via the sensor. The sensor also contains a temperature electrode that monitors surface temperature of the patient's skin. All this data is analyzed and digitally stored in a non-volatile manner by the monitor. The resulting DML and F-LAT are displayed on the NC-stat LCD.

5. Intended Use

The NeuroMetrix NC-stat is intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. The NC-stat is intended to be used as an adjunct to and not a replacement for conventional electrodiagnostic measurements.

6. Technological Characteristics and Substantial Equivalence

NeuroMetrix, Inc. believes that the descriptive information and performance test summaries provided in this premarket notification are precise enough to demonstrate the substantial equivalence of the NC-stat to the identified predicate devices. The reasoning process for making the assessment that the devices are substantially equivalent in intended use and technological characteristics are outlined below.

The NC-stat has similar technological characteristics when compared to the two predicate devices listed above. For example, like the TECA TD-10/TD-20 and the Neurotron device, the NC-stat measures the M response and uses this measurement to calculate the DML. In addition, like the TECA TD-10/TD-20, the NC-stat measures the F response and uses this measurement to calculate the F-LAT. All

three devices use electrodes to stimulate the nerve and to detect the resulting CMAP. Although the TECA and Neurotron sensor material is unknown, the NC-stat material has been thoroughly tested and found to fulfill the ISO-10993 criteria for biocompatibility for surface device in contact with skin. NeuroMetrix, Inc. believes that the descriptive characteristics and performance data provided in this premarket notification are precise enough to ensure substantial equivalence.

7. PERFORMANCE TESTING

System testing was performed on the NC-stat in which several complete tests were simulated to obtain all possible test outcomes. The System Level Testing was divided into six test protocols: evaluation of circuit operation, operational testing, response to normal, pathologic and marginal data, system response to user error, system response to defective and malfunctioning disposable sensors, and evaluation of measurement data download. In addition, an evaluation of DMLs acquired by volume conduction and those signals acquired and measured using conventional methods was conducted. These tests demonstrate that the NC-stat yields the appropriate outcome with a high probability. They also demonstrate that the NC-stat conforms to the safety related system and software requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1998

NeuroMetrix, Inc.
c/o Ms. Renee J. Thibeault
Associate Consultant
Medical Device Consultants, Inc.
49 Plain St.
North Attleboro, Massachusetts 02760

Re: K982359
Trade Name: NC-STAT
Regulatory Class: II
Product Code: JXE
Dated: July 01, 1998
Received: July 06, 1998

Dear Ms. Thibeault:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982359

Device Name: NC-stat

Indications For Use:

The NeuroMetrix NC-stat is intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. The NC-stat is intended to be used as an adjunct to and not a replacement for conventional electrodiagnostic measurements.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982359

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)