K 013459

510(k) Summary
for
NC-stat

JAN 1 7 2002

1. SPONSOR

NeuroMetrix, Inc.
62 Fourth Avenue
Waltham, MA 02451

Contact Person: Joseph Burke
Telephone: (781) 890-9989

Date Prepared: October 17, 2001

2. DEVICE NAME

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

3. PREDICATE DEVICES

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

4. INTENDED USE

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

5. DEVICE DESCRIPTION

The NC-stat consists of the following four components:

5.1 A handheld, battery-powered monitor. The monitor contains the electronic circuitry and software required to provide initiate and control the nerve conduction study, acquire and save patient and test information, display

information on the LCD readout, and transmit data to the docking station. LCD displays include the distal motor latency (DML) value, the F-wave latency value, 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 docking station used to download the test data to the onCall Information Management Service via an analog phone line.

5.3 Single-use, disposable biosensors for the median, ulnar, tibial, and peroneal nerves. The tibial and peroneal biosensors are the only new accessories for the NC-stat.

5.4 The onCall Information Management Service for generation of the hardcopy patient test report, which includes test results (distal motor latency, F-wave latency, and associated waveforms) and a comparison of patient results to reference ranges. Reports are sent to the user by facsimile.

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 tibial and peroneal biosensors for use in diagnosing lower limb neuropathies.

6.2 Engineering changes necessary to enable the NC-stat to be used for nerve conduction studies of the lower limbs.

6.3 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

JAN 1 7 2002

NeuroMetrix, Inc.
c/o Ms. Sheila Hemeon-Heyer, Esq. RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K013459
Trade/Device Name: NC-stat
Regulation Number: 882.1550
Regulation Name: Nerve conduction velocity measurement device
Regulatory Class: JXE
Product Code: II
Dated: October 17, 2001
Received: October 18, 2001

Dear Ms. Hemeon-Heyer :

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

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

Enclosure

510(k) Number (if known): K 013459

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K013459

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

(Optional Format 1-2-96)