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510(K) Summary
for
NeuroMetrix NC-stat Sensory Extension

1. SPONSOR

NeuroMetrix, Inc.
One Memorial Drive
Cambridge, MA 02142

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

Date Prepared: November 13, 2000

2. DEVICE NAME

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

3. PREDICATE DEVICE

The NeuroMetrix NC-stat Sensory Extension is substantially equivalent to the original NC-stat (K982359 and K000575) and to the TECA TD10/20 (K802637).

4. DEVICE DESCRIPTION

The purpose of this submission is to obtain clearance to market a modified version of the original NC-stat that was originally cleared for marketing on October 2, 1998 (K982359). The proposed NC-stat has been modified to extend the nerve testing capability to include upper extremity sensory nerves. The modified device can be used for evaluation of both median and ulnar sensory neuropathies.

The NC-stat sensory nerve extension required the addition of adapter clips and ring electrodes and acquisition of the evoked sensory nerve action potentials (SNAPs).

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NC-stat software algorithms were expanded to support the detection of median and ulnar SNAPs when either the median or the ulnar nerve biosensor is used.

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

The NC-stat has the same technological characteristics as the predicate devices. The modified NC-stat is virtually identical to the original NC-stat except for the addition of ring electrodes and software modifications to enable acquisition of evoked SNAPs and calculation of the distal sensory latency (DSL). All of these devices use electrodes to stimulate the nerve and to detect the resulting SNAP.

Clinical testing was conducted to validate that the modified NC-stat is able to reliably measure SNAPs..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Neurometrix, Inc.
c/o Mr. James R. Veale
Vice President, Regulatory Services
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K003508
Trade Name: NC-stat
Regulatory Class: II
Product Code: JXE
Dated: November 13, 2000
Received: November 14, 2000

Dear Mr. Veale:

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) 594-4595. 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 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): K003508

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)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003508

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