AUG 1 2001

K012069

510(k) Summary

Trade Name: **BREVIO**

Common/Classification Name: Nerve Conduction Velocity Measurement Device
21 CFR 882.1550

Neurotron Medical, Inc.
1590 Reed Rd., Suite 102B
Pennington, NJ 08534
800-367-1238

Contact: Jack Guldalian, President

Prepared: June 29, 2001

A. LEGALLY MARKETED PREDICATE DEVICES

K963208 NervePace Nerve Conduction Viewscope (VS 200) Neurotron Medical, Inc.

K843924 Digital Electroneurometer (S-100) Neurotron Medical, Inc.

B. DEVICE DESCRIPTION

The BREVIO is a battery powered (4 AA batteries) hand held device that is utilized to perform motor and sensory nerve conduction testing on peripheral nerves in a clinical setting. It consists primarily of two units, a handheld processor with LCD screen and a stimulator. It may also be coupled with a number of HP inkjet printers to print patient information and results.

The BREVIO automatically picks out the latency and amplitude of waveforms presented to determine the values associated with them. The automatically chosen values may be manually adjusted by the user should the user feel the necessity to manually make such a change.

The BREVIO has memory storage of 28 waveforms for later viewing and printing of the test results.

C. INTENDED USE

The BREVIO is intended for use for the measurement of nerve response

latency and amplitude in the diagnosis and monitoring of peripheral neuropathies.

Indication for use:
The BREVIO is intended to be used as a waveform display nerve conduction monitor. It displays the latency value derived from an action potential. The display shows the latency value in milliseconds from the trigger to the onset. The internal circuitry has the complete waveform from which the latency value is derived and this is delivered to the digital storage oscilloscope for compete waveform display.

The latency value is important in the diagnosis of median nerve dysfunction. The physician can use the BREVIO to examine the features of the waveform generated by the stimuli. The physician can determine the action potential latency, amplitude configuration and duration.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The BREVIO is a medical device that has the same indication, intended use and target population as the legally marketed predicate devices.

The BREVIO has the same technological characteristics as the predicate devices.

The BREVIO has incorporated a change in the software that allows the device to automatically pick out the latency and amplitude of waveforms presented to determine the values associated with them. These automatically chosen values may be manually adjusted by the user should the user feel the necessity to manually make such a change or adjustment based upon the user's experience or analysis. In addition the BREVIO has incorporated the mechanical features of both the NERVEPACE® ViewScope™ (200 VS) and Digital Electroneurometer S-100 into a single device.

E. TECHNOLOGICAL CHARACTERISTICS

The BREVIO operates utilizing four AA Alkaline batteries with an output of 9V. It has a graphical LCD display format of 128 x 112 pixels displaying motor and sensory nerve responses.

The BREVIO is capable of detecting motor response signals down to 100 microvolts covering motor and F wave responses. Sensory signal

responses can be detected to 5 microvolts. Latency detection capability covers the time range from 0 to 45 milliseconds. Amplitudes of signal responses can be detected in the range of 5 to 10,000 microvolts. Once the waveform is recorded the system will determine in the case of motor responses the onset latency value and baseline peak amplitude. For sensory responses, the peak latency value and baseline to peak amplitude value will be reported. These values will appear on the screen display and in the printed report.

The memory of the device is capable of storing up to 28 waveform responses.

The maximum stimulator output is 300 volts, pulse width 250 microseconds.

F. TESTING

Bench testing has been done with this device demonstrating that it meets design controls.

Comparative human testing was done demonstrating a high correlation between the BREVIO device and a predicate device for latency and amplitude comparison.

G. CONCLUSIONS

Design specifications, comparison to predicate device specifications and testing has demonstrated that this BREVIO device meets design requirements and is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Neurotron Medical, Inc.
c/o Mr. T. Whit Athey
C. L. McIntosh & Associates
12300 Twinbrook Parkway
Suite 230
Rockville, Maryland 20852

Re: K012069
Trade/Device Name: BREVIO
Regulation Number: 882.1550
Regulatory Class: II
Product Code: JXE
Dated: July 2, 2001
Received: July 2, 2001

Dear Mr. Athey:

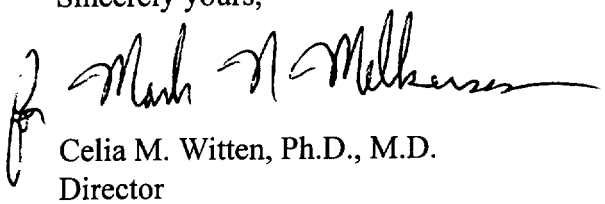
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 requirements, 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,



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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K012069

Device Name: BREVIO

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

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

510(k) Number K012069