DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1997

Mr. Jack Guldalian
Neurotron Medical
P.O. Box 6480
Lawrenceville, New Jersey 08648

Re: K963208
Trade Name: NERVEPACE ViewScope Model 200VS
Regulatory Class: II
Product Code: 84JXE
Dated: April 24, 1997
Received: April 29, 1997

Dear Mr. Guldalian:

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 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

510(k) Number (if known): K963208

Device Name: NERVEPACE ViewScope Model 200VS

Indications For Use:

The Nervepace® ViewScope 200VS is intended to be used as a waveform display nerve conduction monitor. Currently the digital electroneurometer (K843924A ) displays the latency value derived from an action potential. This is accomplished by setting a threshold value into the circuitry and when the onset of the action potential reaches the threshold value it trips the timing circuit and the display shows the latency value in milliseconds from the trigger to the onset. The internal circuitry of the electroneurometer has the complete waveform from which the latency value was derived and this can be delivered to a digital storage oscilloscope for complete waveform display.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K963208

Prescription Use X
(Per 21 CFR 801.109)

~~OR~~ ~~Over-The-Counter Use~~

(Optional Format 1-2-96)