NOV 2 4 2000

K001692

V. 510(k) SUMMARY

Submitted by: Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, VA 20166
Phone: (703) 904-9600
Fax: (703) 904-7870

Contact Person: David B. Jones

Date Prepared: September 1, 2000

Proprietary Name: NEURO SCAN MEDICAL SYSTEMS
Model Nos.: Medicor® 8

Common Name: EMG/EP System

Classification Name:

882.1550	Nerve Conduction Velocity Measurement
882.1870	Evoked Response Electrical Stimulator
882.1890	Evoked Response Photic Stimulator
882.1900	Evoked Response Auditory Stimulator
890.1375	Electromyograph

Classification Name: Nerve Conduction Velocity Measurement (JXE)
Evoked Response Electrical Stimulator (GWF)
Evoked Response Photic Stimulator (GWE)
Evoked Response Auditory Stimulator (GWJ)
Electromyograph (IKN)

Predicate Device: Neurosoft Medical EMG/EP systems: Advantage (A3000) and Medicor® (K973355 and K000812), and A4000/Medicor® System (K001562)

Device Description: The Neuroscan Medical Systems Medicor® 8 is a high-end device that represents the leading edge of EMG/EP technology and provides the clinician with a versatile, comprehensive, user-friendly system with options, including EEG. With a powerful 96KHz amplifier, 12 bit resolution, eight channels, touch controls, high-resolution flat screen display, and two 400V stimulators, the Medicor® 8 is technology based EMG/EP. Medicor® 8's report generator and patient database will automatically tabulate and store test data, and perform abnormal report tagging and off-line analysis. Each laboratory can build its own database for comparisons. Results and data interpretation can be entered directly, via local network or even across the Internet.

Intended Use: The Neurosoft **Medicor® 8** system is intended for the measuring, recording and analysis of the of the electrical activity of a patient's brain and/or neuromuscular functions through the attachment of multiple electrodes at

various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EMG/EP.

Technological Characteristics:

The Neurosoft Medicor® 8 EMG/EP system's technological characteristics are the same as the Advantage 3000/Medicor® EMG/EP systems and the A4000 (Comperio)/Medicor® System. The Neurosoft Medicor® 8 EMG/EP system has the same technological characteristics as the approved predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

Mr. David B. Jones
Regulatory Affairs/Quality Assurance Manager
Neurosoft, Inc.
5700 Cromo, Suite 100
El Paso, Texas 79912

Re: K001692
Trade Name: Neurosoft Medicor® 8 System
Regulatory Class: II
Product Code: JXE, GWF, GWE,GWJ, IKN
Dated: September 1, 2000
Received: September 20, 2000

Dear Mr. Jones:

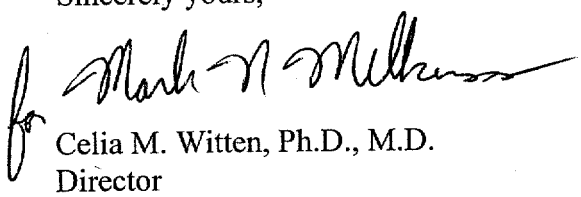
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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

IV. Statement of Indications for Use

Applicant: Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, VA 20166
Phone: (703) 904-9600
Fax: (703) 904-7870

510(k) Number: K001692

Device Name: Neurosoft **Medicor® 8** system

Indications For Use: The Neurosoft **Medicor® 8** system is intended for the ~~measuring~~, recording and analysis of the electrical activity of a patient's neuromuscular functions and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EMG/EP.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001692

Prescription Use ✓ or Over-the-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)