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K974748

FDA 510(k) Summary

Section 807.92

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Date of preparation: 10/25/97

(a)(2). Name of the Device: Neurometric Analysis System (NAS). **Classification name:** EEG Frequency Spectrum Analyzer.

(a)(3). Predicate/legally marketed devices upon which substantial equivalence is based: Cordis Brain State Analyzer (no FDA information available); TECA Corporation Neurolab I, II (K844481), Brain Mapper (K890-881), Neuromapper 386 (K894889); Nicolet BEAM I, II (no FDA 510(k) information available); Pathfinder II (K801604) Brain Functional Map (K843598); Cadwell Laboratories, Inc. 8400 (K860801) and Spectrum 32 (K860801 reference); Lexicor Medical Technology Neurosearch-24 (K904269), Neurosearch-4 (K920038); Neuroscience, Inc. Map-10 EEG (K840430), Neuromapper 1620 (K870263); Biologics Systems Corporation, Inc., Modified Brain Atlas III (K854362), Bio-Logic Automatic Event Analysis (K951594); Quantified Signal Imaging, Inc. QSI-9500 (K904294), QSI-9200 (FDA 510(k) information not available); Stellate Systems, Inc. Rhythm Software (K912938).

(a)(4). Device Description: The Neurometric Analysis System (NAS) is a software program for the post-hoc statistical analysis of the human electroencephalogram (EEG). EEG recorded on a separate device (i.e., the host system) is transferred to the NAS for display and user-review. The system requires that the user select approximately 2.00 minutes of artifact-free, eyes-closed, resting EEG from the recording for analysis. Analysis consists of the Fast-Fourier Transformation (FFT) of the data to extract the spectral power for each of the four primary frequency bands (delta, theta, alpha, and beta), and frequency information from the EEG. The results of this analysis are then subjected to univariate, bivariate, and multivariate statistical analyses and displayed in statistical tables and topographical brain maps of absolute and relative power, power asymmetry, and coherence for 19 monopolar and 8 selected bipolar derivations of the EEG. In all over 1200 measures are derived for comparison against a carefully constructed and statistically controlled age-regressed, normative database in which the variables have been transformed and confirmed for their Gaussian distribution. Each variable extracted by the analysis is compared to the database using parametric statistical procedures that express the differences between the patient and their appropriate age-matched reference group in the form of Z-scores. Multivariate features are compared to the normative database using

Mahalanobis Distance Statistics. The Mahalanobis Distance statistic controls for the inter-relationship of the measures of brain cortical function in the feature set, and provides an accurate estimate of their difference from normal. The multivariate measures permit an evaluation of regional indices of brain function that reflect the perfusion fields of the brain. Extracted feature sets are further analyzed to determine if the pattern of 'hits' (statistically significant feature score values identified for the patient) are consistent with patterns of 'hits' identified in prior neurometric evaluations of clinical patients with known disorders. A step-wise discriminant analysis program classifies the patient in terms of their similarity to known neurometric-defined patterns of abnormality, providing a probability estimate of the patient's profile with the average profile of groups of individuals constituting the normative and clinical database. The discriminant classification program is restricted by confining potential outcomes to specific patient symptoms derived from the patient history profile. Established discriminant functions were evaluated through the use of Receiver Operating Characteristic (ROC) curves for their sensitivity and specificity. The outcome of the statistical analysis is presented in report form that includes (a) patient demographic and history information, (b) selected EEG epochs, (c) statistical tables of monopolar, bipolar, and multivariate extracted feature values, and topographical brain maps. This information is to be read and interpreted within the context of the current clinical assessment of the patient by the attending physician. The decision to accept or reject the results of the neurometric analysis, and incorporate these results into their clinical appraisal of the patient, is dependent upon the judgment of the attending physician.

The Neurometric Analysis System is complete in a set of five 3.5 diskettes, which contains a demonstration program with sample neurometric studies, the NAS program, and the print program. The NAS was designed for implementation under DOS and Windows, and programmed using C++. The user interface was carefully designed and implemented to permit the program to easy to use, highly reliable in its performance. A variety of control procedures are used to record steps used in program usage, and the conduct of the analysis to insure appropriate function and operation of the software. The NAS can be installed in any appropriately configured IBM-compatible computer system, including systems designed specifically for the recording of digital EEG. The system functions with a wide-range of standard computer platforms and input-output devices, and printers.

(a)(5). Statement of Indications of Use: Indications for the use of the Neurometric Analysis System (NAS) are as follows:

Indications of Use

The Neurometric Analysis system is to be used by qualified medical profedssionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG).

(a)(6). Comparison to Predicate Devices: The Neurometric Analysis System uses accepted methods of data selection and analysis to extract the feature measures upon which statistical determination of normal/abnormal are made, and from which derivations of probability estimates of clinical classification are derived. The neurometric method of

EEG selection, analysis, and interpretation have been previously implemented, in whole or in part, in a variety of digital EEG and analysis systems marketed in prior years for the quantitative analysis of the EEG in Man. The NAS database was carefully constructed to control for potential sources of Type I and Type II errors in the use of database comparisons in clinical electrophysiological assessment of the human EEG. The purposeful, easy to use, and reliable design of the NAS has been enhanced relative to these earlier systems through the careful consideration of user interactions with this technologically advanced method of analysis.

(b). Non-clinical and Clinical Tests: The Neurometric Analysis System's design and implementation was based upon the results of an extensive, 20-year effort to construct a viable normative and clinical database at the Brain Research Laboratory (BRL) at New York University's Medical Center. The NAS incorporates the basic methods of data collection, data selection, analysis, and interpretation developed at the BRL during the conduct of numerous government and privately funded normative and clinical database projects.

(b)(1). Non-clinical Testing: Non-clinical testing of the NAS included the evaluation of the algorithms and statistical methods used for data analysis. Specifically, control signals, in the form of signal generated waveforms, were analyzed for frequency and power. EEG signals were analyzed for conformity between the host digital EEG system and the NAS. The NAS includes a feature that reproduces sampling frequency in the host digital EEG system, and permits the visualization and evaluation of the EEG waveforms for accuracy between the host system and the NAS translation. In addition, data obtained in previous implementations of the neurometric method were evaluated for consistency and accuracy--the results of the NAS's analysis of stored subject data had to conform to that of the prior analysis (which was conducted using the same method and procedures, algorithms and method of analysis as that implemented on the NAS).

(b)(2). Clinical Testing: The ability of the NAS to accurately translate and present EEGs from clinical patients was confirmed by the nonclinical testing. In order for the NAS to be an effective implementation of the neurometric method for clinical use, the results of the analysis (both statistical tables and topographical brain maps) had to be in agreement with the results of the analysis conducted on the host system used in the processing of patient information at the Brain Research Laboratory. In addition, the outcome of the discriminant analysis had to be consistent, not resulting in errors of misclassification (that is, the classification on the NAS had to be consistent with that of the host system used to perform the neurometric analysis at the BRL). These tests confirmed that when eyes-closed, resting, and artifact-free EEG was selected for analysis, the results were reproducible within an acceptable degree of variation consistent with reliability estimates identified in the normative studies.

Subjects upon which this device has been tested included individuals who ranged in age from 6 to 90 years, and who were either volunteers or clinical patients referred for neurometric evaluation to the Brain Research Laboratory by the Department of Psychiatry

and Department of Neurology at New York University Medical Center. The results of the analysis were conveyed to the referring physician who was asked to use the information as an adjunct to their clinical interpretation of the patient's traditional EEG. The information was provided in report form (including EEG epochs selected for analysis, statistical tables and topographic brain maps, and the result of the discriminant analysis) to permit the physician to determine its relevance to their clinical evaluation and diagnosis or treatment of the patient. When the results are used in this manner, the likelihood of introducing error into diagnosis and treatment is substantially reduced. That is, the test is viewed as an adjunct to the evaluation of the patient, and does not serve as a primary basis for the diagnosis.

Potential adverse effects of the use of the device are known if the Neurometric Analysis System is used as a stand-alone diagnostic system (a use that is specifically contraindicated by NxLink and the system's developers) in the absence of other clinical data from more traditional means of patient evaluation. Relying only upon the use of a single index (such as relative power, or the topographical maps alone) without reviewing the traditional EEG, the epochs selected for analysis, or the complete set of statistical summary tables is also contraindicated and a source of potential error. Additional sources of error could arise from the inappropriate selection of EEG (selecting artifacted EEG epochs, or selecting EEG representative of other states, such as drowsiness or eyes-open EEG, or by purposely selecting conditions for testing other than those specified. Additionally, it is possible that errors will occur through the purposeful falsification of symptoms in the patient history, and patient age.

(b)(3) Conclusions Drawn From Non-Clinical and Clinical Testing: The appropriate use of the Neurometric Analysis System as an adjunct to the traditional visually-appraised EEG provides the user with the ability to quantify EEG variables and use them to answer questions drawn from their clinical experience with the patient. When used by an experienced, qualified practitioner, or under the proper supervision of a qualified medical professional, the NAS is concluded to be a useful and beneficial addition to the array of clinically accepted medical tests and devices used to evaluate brain structure and function.

The results of non-clinical and clinical testing conducted over the past 20 years demonstrates that the NAS is both safe and effective for the quantitative analysis of the eyes-closed resting EEG in the alert human subject. Used to determine if the EEG is normal or abnormal, and if abnormal, to statistically characterize the distribution of selected neurometrically-derived features by their probability of being similarly distributed in specified groups of clinical patients, the NAS provides information that both complements and supplements the outcome of the analysis of a traditional EEG. This information, when properly used in conjunction with other clinical tests as a safe and effective adjunctive aid to diagnosis, treatment planning, and treatment follow-up of the neurologic and psychiatric patient.

Compared to its predicate devices, the Neurometric Analysis System's inclusion of specific, appropriate, and effective statistical controls over the method of data selection

and analysis, the scientific rigor involved in the construction, refinement, and application of the normative and clinical databases, and the potential for providing practitioners with sensitive and specific quantitative indices of brain structure and function that is both safe and effective, suggests that the NAS is a significant advancement in the use of quantitative technology in neurology, psychiatry, and clinical neuropsychology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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Duane Shuttlesworth,Ph.D.
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1706 Gaillard Place
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APR - 9 2012

Re: K974748
Trade/Device Name: Neurometric Analysis System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLU
Dated (Date on orig SE ltr): April 8, 1998
Received (Date on orig SE ltr): April 13, 1998

Dear Mr. Shuttlesworth:

This letter corrects our substantially equivalent letter of July 10, 1998.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974748

Device Name: Neurometric Analysis System

Indications For Use: The Neurometric Analysis System (NAS) is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974748

Prescription Use X
Per 21 CRF 801.109

OR

Over-The-Counter Use

(Optional Format 1-2-96)