K962447

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SUMMARY OF SAFETY AND EFFECTIVENESS

Date: June 21, 1996

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Subject Device: Equinox™ Digital EEG System

Predicate Device: K930080, HydroDot NeuroMonitoring System
K905435B UNIQUANT™ System

This submission describes an EEG recording system that is comprised of a combination of components described in two separate 510(k) submissions. The system components are Biosensor electrodes, e-Net Headpiece, Patient Module, Fiber Optic Cable, DSP Interface Cable, Computer Hardware and Software Application.

The first three items were originally discussed in Physiometrix Premarket Submission K930080, HydroDot NeuroMonitoring System. Subsequently several modifications have been submitted to the FDA for review. This file, Physiometrix Premarket Submission K962157, NeuroLink NeuroMonitoring System, is pending substantial equivalence decision. Therefore, all applicable items contained in K962157 have been duplicated in this submission.

The last two items, the computer hardware and software application are described in Neuro Concepts K905435B, UNIQUANT™ System. The software application described in this submission is called the Administrator. A business agreement has been arranged between Physiometrix and Neuro Concepts, Inc. whereby the Administrator software application will be incorporated into the Physiometrix System by Neuro Concepts, Inc.

Classification: Class II, CFR 21 Part 882.1320, Cutaneous Electrodes
Class II, 21 CFR Part 882.1400, Electroencephalograph
Class II, 21 CFR Part 882.1835, Physiological Signal Amplifier

Description:

The Equinox™ Digital EEG System incorporates products produced by Physiometrix and Neuro Concepts to provide a superior system for EEG recording that provides cost benefits to the user.
The Equinox™ System features several Physiometrix products including the Biosensor electrodes, e-Net headpiece, Patient Module, fiber optic cable and DSP Interface Card and computer hardware. The last component of the system is the Neuro Concepts software described in K905435B UNIQUANT™ System.

The Equinox™ is an EEG system that offers a choice of paper or paperless approaches to reading of EEG records and automatic archival of EEG data onto optical disks. The highest priority of the system is to ensure the quality of the EEG data acquisition and storage thus preserving the full fidelity of the raw analog EEG waveform for reproduction onto paper or for display on a computer monitor.

EEG data that is acquired on the Equinox™ System is always archived directly onto optical disk with no means available to the system operator to modify or process the raw digitized data.

Intended Use:

The Equinox™ System has the same intended use as the Neuro Concepts UNIQUANT™ System, that is preserving the full fidelity of the original EEG waveform data in the EEG patient population while providing tools for displaying and printing EEG waveforms for review and interpretation by trained health care professionals.

Technology:

The Physiometrix Equinox™ System has the same intended use as the predicate devices described in K905435B, UNIQUANT™ System, which is preserving the full fidelity of the original EEG waveform data in the EEG patient population while providing tools for displaying and printing the waveforms for analysis and interpretation by trained health care professionals.

The Equinox™ System is similar to the UNIQUANT™ System in that they use identical computer hardware and software applications.

The Equinox™ System differs mainly from the UNIQUANT™ in that the Equinox™ is comprised of all the components necessary to acquire and display waveforms. The UNIQUANT™ system does not include electrodes or electrode placement tools that are a part of the Equinox™ System. These components are described in the Physiometrix K930080.

Conclusion:

The requirements of the Equinox™ System are consistent with the basic functionality of the predicate devices as well as conventional EEG machines that acquire and display EEG records on paper.

Since there is no change in intended use from either of the predicate devices, there are no failure modes or latent design flaws in the software that would be expected to result in physical injury to the patient. Thus, the software that controls this device poses no

substantial risk or danger to the patient. It therefore meets the criteria for minor concern as outlined in the FDA Draft Reviewer Guidance for Computer Controlled Products. The concern is minor because even if there is an inadvertent misuse of the software, there is no risk or danger to the patient.