510(k) Summary K061908

NOV - 6 2006

Company Name: VIASYS NeuroCare, Inc.

Device Name: NicoletOne System V32 Amplifier with Oximetery

510(k) Sponsor, Contact:

VIASYS NeuroCare, Inc.
5225 Verona Road
Madison, WI 53711
Glen Hermanson
Mange of Global Quality
Phone: (608) 441-2065
Fax: (608) 441-2007

Summary Date: September 29, 2006

Common Name: Electroencephalograph

Classification Name: Electroencephalograph, CFR 882.1400, Product Code: GWQ, Class II

Predicate Device(s): K964280 DG Nervus

K990522 Digital EEG and Sleep Acquisition System with or Without Pulse Oximetery Feature (Waratah and Cardinal Digital EEG/Sleep Acquisition System)

1.0 Description of Device

The NicoletOne System V32 Amplifier is a stand alone EEG amplifier embodiment. The V32 Amplifier supports 32 channels of patient input. The EEG electrode interface (headbox) is integral to the amplifier. The NicoletOne System V32 Amplifier provides an electrophysiological amplifier variation for use with the NicoletOne System.

An optional external passive headbox, the HB3, is available for use with the V32 Amplifier. An optional Original Equipment Manufacturer (OEM) supplied pulse oximeter can be provided as a signal input from the patient. The optional OEM pulse oximeter feature is supported by a NONIN XPOD pulse oximeter module and NONIN Pure light 8000X Series Pulse Oximeter Sensor.

The V32 Amplifier has a system evaluation signal (calibration signal) to verify system signal pathways, electrode impedance display on the amplifier and uses an Ethernet connection to communicate to the NicoletOne System computer. No physiologic alarms are supported by the V32 Amplifier.

1.1 Clinical Application

The V32 amplifier is used in hospitals and clinical environments such as Neurology clinics and Sleep Labs to support clinical measurement and monitoring of electroencephalograph signals (EEG), pulse oximetery and other physiologic signals. The V32 Amplifier does not support any user alarms with regard to pulse oximeter limits. The pulse oximeter feature is applied to support EEG diagnosis.

2.0 Intended use of Device

The intended use of the NicoletOne System V32 Amplifier with Oximetery is:

> The NicoletOne System V32 Amplifier is a stand alone electroencephalography (EEG) amplifier for the recording of electrical signals from the brain. An optional feature of pulse oximetery (SpO_2) is available.

3.0 Technological Characteristics

Significant technical characteristics of the V32 amplifier are equivalent to those of the predicate amplifier. The features and specifications that are not identical, such as DC Input Tolerance, EEG Bandwidth and Calibration Waveform (system evaluation signal), do not raise new questions of safety or effectiveness.

Amplifier Feature	Predicate U32 Amplifier	V32 Amplifier
Number of Channels	40: 32 Differential, 8 Bipolar	32
Interface with XPod Pulse Oximetery	Yes	Yes
Computer Interface	USB	Ethernet
Filter Bandwidth	0.16 to 500Hz	0.053 to 500 Hz
Common Mode Rejection	>110dB at 0.16Hz to 70Hz	>110dB at 50/60 Hz
Common Mode Input Impedance	≥ 100 MegOhm	> 100 MegOhm
DC Input Tolerance	±250mV	±350mV
Electrode Impedance Test	Yes (Continuous)	Yes (Continuous and as selected by the user)
Impedance Indicator	Yes	Yes
Optional External Headbox	No	Yes (HB3)
Patient Event Input	Yes	Yes
Alarms	No	No
Safety Standards Compliance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26 ISO 9919

4.0 Data Summary

Testing of the NicoletOne System V32 Amplifier with Oximetery was performed in compliance with the VIASYS NeuroCare, Inc. design control process. Testing included:

1. Software verification and validation,
2. Hardware and system verification of conformance to specifications, and
2. Declaration of safety standard compliance prior to commercial distribution.

5.0 Conclusions

The safety and effectiveness of the NicoletOne System V32 Amplifier with Oximetery was demonstrated by testing in compliance with the VIASYS NeuroCare Design Control process. The intended use and technology of the NicoletOne System V32 Amplifier with Oximetery is the same as the predicate device. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Viasys Neurocare, Inc.
C/o Gary Syring, Principal Consultant
Quality and Regulatory Associates, LLC
800 Levanger Lane
Stoughton, WI 53589

NOV - 6 2006

Re: K061908
Trade/Device Name: NicoletOne System V-32 Amplifier
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalogram - Neurology
Regulatory Class: Class II
Product Code: GWQ
Dated: September 29, 2006
Received: October 4, 2006

Dear Mr. Syring:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 DGRND
D.O.

f/t: DXV: 11- 02 - 06

Indications for Use

510(k) Number (if known): K061908

Device Name: NicoletOne System V32 Amplifier with Oximetery

Indications for Use:

NicoletOne System V32 Amplifier is a stand alone electroencephalography (EEG) amplifier for the recording of electrical signals from the brain. An optional feature of pulse oximetery (SpO_2) is available.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K061908