K 103140

APR - 8 2011

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

1	**Submitter Information**	
	Name	CareFusion 209, Inc.
	Address	1850 Deming Way, Middleton, WI 53562
	Phone number	608-829-8655
	Fax number	608-829-8769
	Establishment Registration Number	3008289288
	Name of contact person	Robert J Burdge
	Date prepared	6 April 2011
2	**Name of Device**	
	Trade or proprietary name	Nicolet Wireless EEG Amplifier
	Common or usual name	Amplifier, Electroencephalograph
	Classification name	Electroencephalograph
	Classification Panel	Neurology
	Device Class	Class II
	Regulation	21 CFR 882.1400
	Product Code(s)	GWQ, GWL
3	**Legally marketed device(s) to which equivalence is claimed**	

510(k) #:	Cleared on:	Name	Code:
K061908	11/06/2006	NicoletOne V32 Amplifier with Oximetry	GWQ
K090957	05/28/2009	Blackrock Neuroport Biopotential Signal Processing System	GWL
K060523	03/28/2006	NeuroPort Instrument	GWQ
K060803	05/02/2006	gUSBamp	GWL
K040113	02/18/2004	Sandman SD20 Amplifier	GWL
K033475	01/07/2004	Nihon Kohden WEE-1000 Wireless Amplifier	GWQ
K003175	12/27/2000	Siesta Compumedics	GWQ

	Reason for 510(k) submission	The changes addressed in this submission include: • Addition of wireless communication capability between the amplifier and the NicoletOne base system • Increased channels and sampling rates • Battery or Mains power
4	**Device Description**	The Nicolet Wireless Amplifiers are used in a wide variety of EEG applications including: Ambulatory (at home or in transit to home), OR, LTM, EEG, Sleep and ICU. The proposed amplifiers are small portable devices that can run on main electrical A/C power or use a portable battery pack.

	Device Description (cont)	The proposed device consists of two models designated as the 32 channel and the 64 channel amplifier. These units can acquire from up to 32 or 64 channels, they can be grouped or "cascaded" together for more channels. The amplifiers are capable of acquiring a variety of electrophysiological signals at variable sampling frequencies. These signals include EEG, EKG, EMG, EP, temperature, blood pressure, pulse, and other signals standard to neurological and sleep testing. The amplifiers have wireless capability and a battery pack for mobile data acquisition. Wireless access points collect the wireless data transmissions. The amplifiers can be connected to the Ethernet by a cable and also to AC power. The amplifiers are IP addressable and can be connected directly to a network device. In all situations the amplifiers store a copy of the data locally to allow for data back-up. This amplifier provides storage and subsequent transmission of data that is not transferred live when the amplifier is in out of range situations.
5	**Intended use of the device**	The Nicolet Wireless EEG Amplifier is intended to be used as a front end amplifier to acquire, store, and transmit electrophysiological signals in a wired or wireless mode for the Nicolet Neurodiagnostic system.

6 Summary of the technological characteristics of the device compared to the predicate device

	Characteristic	New Device Nicolet Wireless EEG Amplifier	Predicate [Device Name] [510(k) number]
	Interface to Amplifier	Wired Ethernet (10/100baseT) or Wireless Ethernet (802.11b/g)	Wired Ethernet (10/100baseT)or Wireless Ethernet (802.11b) Substantially equivalent to the Nihon Kohden WEE-1000 Wireless Amplifier (K033475)
	Power	Battery or 110/220VAC	110 VAC, Battery and USB Port Substantially equivalent to the Nihon Kohden WEE-1000 Wireless Amplifier (K033475)
	System components	Patient Cable, Amplifier, CPU and a Display Monitor; Telemetry unit and access point	System components comprised of telemetry unit, Electrode junction box and access point to operate with the current NK commercially available EEG devices Substantially equivalent to the Nihon Kohden WEE-1000 Wireless Amplifier (K033475)
	Number of Signal Recording Channels	Up to 32 or 64 channels	32 and up to 128 with one device; Up to 256 by cascading two devices Substantially equivalent to the Blackrock Neuroport Biopotential Signal Processing System (K090957)

	Clinical Application Environment	For use in research institutions, clinic, hospital, operating room and epilepsy evaluation environments	For use in research institutions, clinic, hospital, operating room and epilepsy evaluation environments Same as the NicoletOne V32 Amplifier (K061908)
	A/D Conversion	A/D Conversion- 24 Bit	A/D Conversion- 24 Bit Same as gUSBamp (K060803)
	Sampling Rate	125, 250, 500, 1000, 2000, 4000, 6000, 8000, 10000, 12,000 16,000, 32,000, 48,000Hz	Up to 32,000 Hz Substantially equivalent to the Sandman SD20 Amplifier (K040113)
	PERFORMANCE DATA		
7	**SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE**		
	Performance Test Summary-New Device		
	Characteristic	Standard/Test/FDA Guidance	Results Summary
	1. Basic safety	IEC 60601-1	The proposed device passes the applicable tests and standards.
	2. Programmable Electrical Medical Systems	IEC 60601-4	The proposed device passes the applicable tests and standards.
	3. Usability	IEC 60601-6	The proposed device passes the applicable tests and standards.
	4. EMC Compatibility	IEC60601-1-2	The proposed device passes the applicable tests and standards.
	5. Collateral Safety	IEC 60601-1-1	The proposed device passes the applicable tests and standards.
	6. Electroencephalographs	IEC 60601-2-26	The proposed device passes the applicable tests and standards.
	7. Risk Management	ISO 14971	The proposed device passes the applicable tests and standards.
	8. Biocompatibility- non contact device	ISO 10993-1	The proposed device passes the applicable tests and standards.
	9. FCC Specific Absorption Ratio (SAR)	FCC Part 15C; FCC OET Bulletin 65, Supplement C	The proposed device passes the applicable tests and standards.
	10. Battery safety	UN/DOT 38.3 Transportation testing for lithium batteries	The proposed device passes the applicable tests and standards.
	Summary Discussion of Bench Performance Data		
	The Nicolet EEG Wireless Amplifier device passed all specified test requirements. The validation and verification testing confirmed this device meets user needs and design inputs for an EEG amplifier. Testing also confirmed physical attributes and device performance meet the requirements of the standards listed in the performance testing summary above. These standards address safety, biocompatibility, EMC compatibility, risk, usability, and radiated energy.		
8	**SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL**		

	EQUIVALENCE AND/OR OF CLINICAL INFORMATION
	Clinical Performance Data/Information Clinical testing was not performed with this device.
9	**CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA**
	The Nicolet Wireless EEG Amplifiers meet the functional claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to The K061908- NicoletOne V32 Amplifier with Oximetry, the K090957 Blackrock Neuroport Biopotential Signal Processing System, the K060523 NeuroPort Instrument, the K060803 gUSBamp, the K040113 Sandman SD20 Amplifier, the K033475-Nihon Kohden WEE-1000 Wireless Amplifier and the K003175- Siesta Compumedics described in the submission. The claim for substantial equivalence is supported by the information provided in this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Carefusion 209, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street, NW
Buffalo, MN 55313

APR - 8 2011

Re: K103140
Trade/Device Name: Nicolet Wireless EEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWL and GWQ
Dated: January 20, 2011
Received: January 21, 2011

Dear Mr. Job:

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,

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

Indications for Use

510(k) Number (if known):__K103140_____

Device Name: Nicolet Wireless EEG Amplifier

The Nicolet Wireless EEG Amplifier is intended to be used as a front end amplifier to acquire, store, and transmit electrophysiological signals in a wired or wireless mode for the Nicolet Neurodiagnostic system.

Prescription Use _ XXX_
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter use____
(21 CFR Part 801 Subpart C)

(PLEASE DO NO WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Quynh Hoang

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K103140