APR 2 5 2012

510(k) Summary
CareFusion Nicolet EDX with Synergy Software

[A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92]

1. Submitter / 510(k) Holder

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Date prepared	April 18, 2012

2. Device Name

Proprietary name	CareFusion Nicolet EDX with Synergy Software	
Common name	Diagnostic Electromyograph	
Device Class	Class II	
Classification name	Evoked Response Electrical Stimulator [primary] Diagnostic Electromyograph Nerve Conduction Velocity Measurement Device Non-normalizing Quantitative Electroencephalograph Software Evoked Response Auditory Stimulator Evoked Response Photic Stimulator Evoked Response Mechanical Stimulator	
Product Code, Regulation	GWF	21 CFR §882.1870 [primary]
	IKN	21 CFR §890.1375
	JXE	21 CFR §882.1550
	OLT	21 CFR §882.1400
	GWJ	21 CRF §882.1900
	GWE	21 CFR §882.1890
	GZP	21 CFR §882.1880

3.	**Predicate Devices**	**510(K) Number**	**Device Name**
		K112052	CareFusion Nicolet EDX with Viking Software
		K965065	CareFusion Synergy Mobile System
		K070109	NeuroMetrix Advance System

4. Device Description

The CareFusion Nicolet EDX system with Synergy Software (Synergy EDX) is designed for the acquisition, display, analysis, reporting, and management of electrophysiological information from the human nervous and muscular systems. The system is designed to perform nerve conduction studies (NCS), needle electromyography (EMG) testing, evoked potential (EP) testing, and intra-operative monitoring (IOM). Synergy EDX provides a variety of tests spanning the various modalities.

The Synergy EDX consists of the following major components:

- Nicolet EDX console base unit;
- Synergy control panel;
- Nicolet amplifier (there are two types available: 2 channel (AT2) with two non-switched amplifier channels and an 8 channel (AT2 + 6) amplifier with two non-switched and six switched amplifier channels;
- Desktop or laptop computer with a keyboard and mouse;
- Display monitor; and
- Synergy Software

The Synergy EDX optional accessories/components consists of the following:

- Nicolet HB6 or HB7 Head Box
- Stimulator probes (RS 10 probe, WR 50 Probe, S403 probe)
- SP1/SP2 electrical stimulator switching units
- Footswitches (single and triple)
- LED goggles
- Patient response button
- Photic strobe
- Headphones or other auditory transducers
- Cart
- Isolation transformer
- Printer

Description of Major Components

Nicolet EDX Console Base:
The console base is an AC mains powered electrical device that houses the core Nicolet EDX hardware, and provides interconnection capability with the rest of the Nicolet EDX hardware and PC. This is exactly the same as in the Nicolet EDX with Viking software system. The PC contains the software.

Synergy Control Panel:
The control panel along with the mouse is the primary user interface for the Nicolet EDX system. The control panel contains a variety of controls that allow the user to access and use the Nicolet EDX system from the touch of a button or knob. This control panel performs similar functions as the Viking control panel from the Nicolet EDX with Viking software system.

Nicolet Amplifiers (AT2 and AT2 + 6):
The Nicolet amplifiers are DC powered electrical devices that record, amplify and transmit responses from the nerve and/or muscle to the Nicolet EDX console base. The AT2 amplifier collects up to two channels of neurophysiological information and the AT2 + 6 amplifier collects up to 8 channels of neurophysiological information. These are exactly the same amplifiers as in the Nicolet EDX with Viking software system.

Personal Computer (PC) with Keyboard and Mouse:
The Nicolet EDX system hardware is used in conjunction with a personal computer (PC), which is offered in either a desktop or laptop configuration. These are exactly the same PCs as in the Nicolet EDX with Viking software system. The Synergy software is supplied preloaded onto the PC.

Display Monitor:
The desktop PC version requires a display monitor which is provided with the Nicolet EDX system hardware. The laptop version does not require a separate display monitor beyond the built-in laptop display; however, an external display monitor may be used if desired. The additional display monitor is facilitated through the connection to an isolation transformer that is included with a desktop PC and available as an optional accessory for laptop based systems. These are exactly the same monitors and isolation transformer as in the Nicolet EDX with Viking software system.

Description of Optional Accessory Components

HB6 and HB7 Head Boxes:
The HB6 and HB7 Head Boxes are passive devices. These are exactly the same head boxes as in the Nicolet EDX with Viking software system. They can be connected to the AT2+6 Amplifier via a cable to allow the electrodes' receptacles to be in closer proximity to the patient.

Electrical Stimulator Probes:
There are three types of electrical stimulator probes available for use with the Nicolet EDX System Hardware: (1) the WR 50 comfort Plus Probe, (2) the RS 10 Comfort Probe and (3) the S403 Probe. These are exactly the same Stimulus Probes as in the Nicolet EDX with Viking software system. The probes connect to the Nicole EDX console base via a cable. Each probe contains a tip that facilitates direct stimulus contact to the patient when activated. The probes can deliver a stimulus ranging from 0 – 400 V / 0 - 100 mA.

SP-1/SP-2 Electrical Stimulus Switching Units:
The SP-1 and SP-2 Stimulus Switching Units allow the user to connect multiple sets of electrodes on the patient for stimulation at different locations. These are exactly the same Stimulus Switching Pods as in the Nicolet EDX with Viking software system.

Footswitch and Triple Footswitch:
The footswitches allow the user to activate defined functions such as electrical stimulation and

initiate acquisition of trace data. Pressing the footswitch activates or deactivates the user defined function. These are exactly the same footswitches and functions as in the Nicolet EDX with Viking software system.

Patient Response Button:
The patient response button allows the patient to respond to a rare stimulus during specific EP testing. This is exactly the same Patient Response Button and function as in the Nicolet EDX with Viking software system. The patient presses the button when the rare stimulus is detected. The Nicolet EDX senses the button press and increments a count.

Visual Stimulators:

(1) LED goggles are available to provide visual stimulation to the patient when the Visual Evoked Potential (VEP) software option is in use. These are exactly the same LED goggles and function as in the Nicolet EDX with Viking software system.

(2) A photic strobe is also a visual stimulus option. This is exactly the same photic strobe and function as in the Nicolet EDX with Viking software system. It can be mounted on an optional stand. Similar to the other visual stimulus; it is used with the VEP option. All three visual stimulators have no controls or indicators and are connected to the Nicolet EDX Console Base Unit. This photic strobe was previously cleared under K921927 and K991054.

Headphones or other Auditory Transducers:
Headphones are available, or other auditory transducers may be used to provide auditory stimulation to the patient through the transducer when the Auditory Evoked Potential (AEP) is in use. Headphones and transducers have no controls or indicators and are connected to the Nicolet EDX Console Base unit auditory stimulator output connectors. These are exactly the same transducers and function as in the Nicolet EDX with Viking software system.

Cart and Printer:
The metal cart provides a convenient way to contain all of the components of the Nicolet EDX System Hardware into one mobile location. The cart has lockable wheels and a convenient handle to facilitate movement of the cart. Two articulating arms are provided for mounting the display monitor and amplifier. There are multiple shelves present to accommodate the placement and storage of various Nicolet EDX System Hardware components and supplies. A retractable keyboard shelf and mouse pad is available. In terms of printing capabilities, a printer equivalent to a DeskJet or Laser printer is available for connection to the system to print reports or screen copies. The cart is exactly the same and functions the same as in the Nicolet EDX with Viking software system.

5. Indications for Use:

The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The

Nicolet EDX with Synergy Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Synergy Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Nicolet EDX with Synergy Software is intended to be used by a qualified healthcare provider.

6 Summary of Technical Characteristics Compared to the Predicate Devices

1. General - Indications

Characteristic	CareFusion 209, Inc. Nicolet EDX with Synergy System (This Submission)	CareFusion 209, Inc. Nicolet EDX with Viking (K112052)	Discussion of Differences
1.1 Indications for Use	The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG). Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Nicolet EDX with Synergy Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Synergy Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System. The Nicolet EDX with Synergy Software is intended to be used by a qualified healthcare provider.	The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG). Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, and Motor Evoked Potentials (MEP). The Nicolet EDX with Synergy Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Synergy Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System. The Nicolet EDX with Viking Software is intended to be used by a qualified healthcare provider.	Identical to the Nicolet EDX with Viking software with the minor addition of the CNV test being a part of the Evoked Potential Modality.
1.2 Warnings	Items related to off-label use or misuse.	Items related to off-label use or misuse.	Identical to the Nicolet EDX with Viking software.
1.3 Contra-indications	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Identical to the Nicolet EDX with Viking software

2. General - Design			
Characteristic	**CareFusion 209, Inc. Nicolet EDX with Synergy System (This Submission)**	**CareFusion 209, Inc. Nicolet EDX with Viking (K112052)**	**Discussion of Differences**
2.1 General systems approach	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Identical to the Nicolet EDX with Viking software
2.2 User input device	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with dedicated control panel.	Identical to the Nicolet EDX with Viking software. (See footnote 1)
2.3 User output device	Digital color display and commercial printers	Digital color display and commercial printers	Identical to the Nicolet EDX with Viking software
2.4 Patient inputs	2 to 8 channel amplifier, isolated	2 to 8 channel amplifier, isolated	Identical to the Nicolet EDX with Viking software
2.5 Signal acquisition	Analog to digital conversion at 48kHz sample rate	Analog to digital conversion at 48kHz sample rate	Identical to the Nicolet EDX with Viking software
2.6 Trigger input (synchronization to external events)	Yes	Yes	Identical to the Nicolet EDX with Viking software
2.7 Trigger output (synchronization for external devices)	Yes	Yes	Identical to the Nicolet EDX with Viking software
2.8 Footswitch for hands-free operation	Yes	Yes	Identical to the Nicolet EDX with Viking software
2.9 Use of standard software platform (Operating System)	Yes Microsoft Windows	Yes Microsoft Windows	Identical to the Nicolet EDX with Viking software
2.10 Customization of protocols	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Identical to the Nicolet EDX with Viking software
2.11 Application flexibility / expandability	Via software update	Via software update	Identical to the Nicolet EDX with Viking software
2.12 Safety Standards	EN/IEC 60601-1:1998 + A1:1991+A2:1995, IEC 60601-1-1:2000 EN/IEC 60601-1-2: Ed. 2.0+A1:2004 IEC 60601-2-40: 1998, Ed:1, UL 60601-1: 2003-04-25 ED1 Rev:2003/06/30, CAN/CSA-C22.2 no. 601.1-M90 Issue:1990/01/01 Rev:2003/11	EN/IEC 60601-1:1998 + A1:1991+A2:1995, IEC 60601-1-1:2000 EN/IEC 60601-1-2: Ed. 2.0+A1:2004 IEC 60601-2-40: 1998, Ed:1, UL 60601-1: 2003-04-25 ED1 Rev:2003/06/30, CAN/CSA-C22.2 no. 601.1-M90 Issue:1990/01/01 Rev:2003/11	Identical to the Nicolet EDX with Viking software

Characteristic	CareFusion 209, Inc. Nicolet EDX with Synergy System (This Submission)	CareFusion 209, Inc. Nicolet EDX with Viking (K112052)	Discussion of Differences
	European Community (CE Mark)	European Community (CE Mark)	
2.13 Patient circuitry isolation	Optic/transformer	Optic/transformer	Identical to the Nicolet EDX with Viking software
2.14 System components	EDX base console including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	EDX base console including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	Identical to the Nicolet EDX with Viking software
2.15 System – computer interface	USB	USB	Identical to the Nicolet EDX with Viking software
2.16 System power supply	Mains (100 – 240 VAC) thru an isolation transformer	Mains (110 – 240 VAC) thru an isolation transformer	Identical to the Nicolet EDX with Viking software
2.17 Amplifier power supply	15 VDC from base console	15 VDC from base console	Identical to the Nicolet EDX with Viking software
2.18 Size (L/W/D) cm	35.6 x 34.3 x 8.6 (base console)	35.6 x 34.3 x 8.6 (base console)	Identical to the Nicolet EDX with Viking software
2.19 Weight kg	3.5 (base console)	3.5 (base console)	Identical to the Nicolet EDX with Viking software

Footnote 1: The Synergy control panel is functionally equivalent to the Viking control panel but the number of controls differs.

3. Design - Acquisition			
Characteristic	**CareFusion 209, Inc. Nicolet EDX with Synergy System (This Submission)**	**CareFusion 209, Inc. Nicolet EDX with Viking (K112052)**	**Discussion of Differences**
3.1 Number of channels	2 to 8	2 to 8	Identical to the Nicolet EDX with Viking software
3.2 CMMR	> 110 dB	> 110 dB	Identical to the Nicolet EDX with Viking software
3.3 Noise	< 0.6uV RMS (from 2 Hz to 10 kHz)	< 0.6uV RMS (from 2 Hz to 10 kHz)	Identical to the Nicolet EDX with Viking software
3.4 Input impedance	>1000 MΩ	>1000 MΩ	Identical to the Nicolet EDX with Viking software
3.5 Low Filter	0.05 Hz to 5 kHz	0.05 Hz to 5 kHz	Identical to the Nicolet EDX with Viking software
3.6 High filter	30 Hz to 20 kHz	30 Hz to 20 kHz	Identical to the Nicolet EDX with Viking software
3.7 Notch filter	50 / 60 selectable	50 / 60 selectable	Identical to the Nicolet EDX with Viking software
3.8 A/D conversion	24 bit	24 bit	Identical to the Nicolet EDX with Viking software
3.9 Sampling rate (cumulative)	384 kHz	384 kHz	Identical to the Nicolet EDX with Viking software
3.10 Time base range	0.01 to 5000 ms	0.01 to 5000 ms	Identical to the Nicolet EDX with Viking software
3.11 Number of Time bases allowed	Multiple	Multiple	Identical to the Nicolet EDX with Viking software
3.12 Trigger mode	Free run, internal, external	Free run, internal, external	Identical to the Nicolet EDX with Viking software
3.13 Signal delay (pre/post)	-3000 to +500 ms	-3000 to +500 ms	Identical to the Nicolet EDX with Viking software
3.14 Impedance meter	500 Ω to 480 kΩ	500 Ω to 480 kΩ	Identical to the Nicolet EDX with Viking software

4. Design - Stimulators

Characteristic	CareFusion 209, Inc. Nicolet EDX with Synergy System (This Submission)	CareFusion 209, Inc. Nicolet EDX with Viking (K112052)	Discussion of Differences
4.1 Electrical Stimulator			
4.1.1 Type	Constant Current or Constant Voltage	Constant Current or Constant Voltage	Identical to the Nicolet EDX with Viking software
4.1.2 Number	1 or 2	1 or 2	Identical to the Nicolet EDX with Viking software
4.1.3 Maximum Output	100mA or 400V	100mA or 400V	Identical to the Nicolet EDX with Viking software
4.1.4 Duration	0.01 to 1 ms	0.01 to 1 ms	Identical to the Nicolet EDX with Viking software
4.1.5 Mode	Single or Train	Single or Train	Identical to the Nicolet EDX with Viking software
4.1.6 Biphasic	Yes	Yes	Identical to the Nicolet EDX with Viking software
4.2 Auditory Stimulator			Identical to the Nicolet EDX with Viking software
4.2.1 Type	Click, Pip, Burst	Click, Pip, Burst	Identical to the Nicolet EDX with Viking software
4.2.2 Intensity	0 to 139 dB pSPL	0 to 139 dB pSPL	Identical to the Nicolet EDX with Viking software
4.2.3 Polarity	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Identical to the Nicolet EDX with Viking software
4.2.4 Tone Frequency	125 to 8000 Hz	250 to 8000 Hz	Similar to the Nicolet EDX with Viking software with the addition of 125 Hz frequency. The additional frequency does not change the indications for use or safety and effectiveness. The Synergy predicate (K965065) has 125 Hz frequency.
4.2.5 Click Duration	0.05 to 1 ms	0.05 to 1 ms	Identical to the Nicolet EDX with Viking software
4.2.6 Side	Left, Right, Both	Left, Right, Both	Identical to the Nicolet EDX with Viking software
4.2.7 Transducers	TDH 39, TIP 300, Bone Vibrator	TDH 39, TIP 300, Bone Vibrator	Identical to the Nicolet EDX with Viking software

5. EMG Application Modules

Characteristic	CareFusion 209, Inc. Nicolet EDX with Synergy System (This Submission)	CareFusion 209, Inc. Nicolet EDX with Viking (K112052)	Discussion of Differences
5.1 Free Run Acquisition	Yes	Yes	Identical to the Nicolet EDX with Viking software
5.2 Nerve Conduction Study (NCS)	Yes	Yes	Identical to the Nicolet EDX with Viking software
5.3 Stimulator Triggered	Yes	Yes	Identical to the Nicolet EDX with Viking software
5.4 Signal Triggered Acquisition	Yes	Yes	Identical to the Nicolet EDX with Viking software
5.5 Spontaneous Activity (SPA)	Yes	Yes	Identical to the Nicolet EDX with Viking software
5.6 Single Fiber EMG (SFEMG)	Yes	Yes	Identical to the Nicolet EDX with Viking software
5.7 Motor Unit Analysis	Yes	Yes	Identical to the Nicolet EDX with Viking software
5.8 F-Wave	Yes	Yes	Identical to the Nicolet EDX with Viking software
5.9 H Reflex (H-Wave)	Yes	Yes	Identical to the Nicolet EDX with Viking software
5.10 Sympathetic Skin Response (SSR)	Yes	Yes	Identical to the Nicolet EDX with Viking software

6. Evoked Potential Application Modules			
Characteristic	**CareFusion 209, Inc. Nicolet EDX with Synergy System (This Submission)**	**CareFusion 209, Inc. Nicolet EDX with Viking (K112052)**	**Discussion of Differences**
6.1 Somatosensory EP (SEP)	Yes	Yes	Identical to the Nicolet EDX with Viking software
6.2 Auditory EP (AEP)	Yes	Yes	Identical to the Nicolet EDX with Viking software
6.3 Visual EP (VEP)	Yes	Yes	Identical to the Nicolet EDX with Viking software
6.4 P300	Yes	Yes	Identical to the Nicolet EDX with Viking software
6.5 ERG	Yes	Yes	Identical to the Nicolet EDX with Viking software
6.6 EOG	Yes	Yes	Identical to the Nicolet EDX with Viking software
6.7 LED Goggles/Photic (Visual EP Flash)	Yes	Yes	Identical to the Nicolet EDX with Viking software

7. IOM Application Modules			
Characteristic	**CareFusion 209, Inc. Nicolet EDX with Synergy System (This Submission)**	**CareFusion 209, Inc. Nicolet EDX with Viking (K112052)**	**Discussion of Differences**
7.1 IOM	Yes	Yes	Identical to the Nicolet EDX with Viking software
7.2 Processed EEG	Yes	Yes	Identical to the Nicolet EDX with Viking software
7.3 MEP	Yes	Yes	Identical to the Nicolet EDX with Viking software

8. New Features				
Characteristic	**CareFusion 209, Inc. Nicolet EDX with Synergy System (This Submission)**	**CareFusion 209, Inc. Synergy System (formerly Oxford Instruments Medical) (K965065)**	**NeuroMetrix Advance (K070109)**	**Discussion of Differences**
8.1CNV	Yes	Yes	No	Identical to the Synergy predicate.
8.2 Automatic Report Narrative Generation	Yes	No	Yes	Identical to the NeuroMetrix predicate
8.3 Electrical Stimulus Automation	Yes	No	Yes	Identical to the NeuroMetrix predicate

7 Summary of Non-Clinical Performance Testing Conducted for the Determination of Substantial Equivalence

Biocompatibility:

CareFusion has demonstrated the biocompatibility of all direct and indirect patient contacting material associated with the CareFusion Nicolet EDX (Synergy EDX) through compliance with ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. Test results have indicated that contacting materials complies with the standard and are safe for its intended use. There are no different materials than in the Nicolet EDX with Viking Software.

Software testing:

The Synergy EDX contains MODERATE level of concern software. The software was designed and developed according to a robust software development process, and was rigorously verified and validated consistent with the following guidelines:

- FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;
- FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99; and
- FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.

The tests results demonstrated that the Synergy EDX complies with its predetermined specifications.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

The Synergy EDX was tested for electrical safety. Test results demonstrated that the Synergy EDX complies with the following standards:

- IEC 60601-1: 1988, Am1: 1991, Am2: 1995, Medical Electrical Equipment, Part 1: General Requirements for Safety; and
- UL 60601-1: 2006, Medical Electrical Equipment, Part 1: Particular Requirements for Safety.

Electromagnetic Compatibility (EMC) testing was conducted on the Synergy EDX according to the applicable standard. Test results indicated that the system complies with the following:

- IEC 60601-1-2: 2001, Am1: 2004, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

Performance Testing – Bench:

The Synergy EDX was tested to assess performance in accordance with requirements of the applicable performance standard. Test results demonstrated that the Synergy EDX met specifications and complies with the following standard:

- IEC 60601-2-40: 1998, Medical Electrical Equipment, Part 2-40: Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment.

Performance Testing – Animal &Clinical:

Animal testing and clinical testing were not needed to demonstrate safety and effectiveness.

8 Conclusion

The technological characteristics and performance data for the CareFusion Nicolet EDX System with Synergy Software demonstrates that it is substantially equivalent to the predicate devices.

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

APR 25 2012

CareFusion 209, Inc.
c/o Mr. Curtis D. Truesdale
Manager, Regulatory Assurance
1850 Deming Way
Middleton, WI 53562

Re: K120979
Trade/Device Name: CareFusion Nicolet EDX with Synergy Software
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, IKN, JXE, OLT, GWJ, GWE, GZP
Dated: March 28, 2012
Received: April 2, 2012

Dear Mr. Truesdale:

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 Form

510(k) Number (if known): K120979

Device Name: CareFusion Nicolet EDX with Synergy Software

Indications for Use:

The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Nicolet EDX with Synergy Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Synergy Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Nicolet EDX with Synergy Software is intended to be used by a qualified healthcare provider.

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

Kristen Bowsher

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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