DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 1, 2017

Cadwell Industries, Inc.
Christopher Bolkan
QA/RA Engineer
909 North Kellogg Street
Kennewick, Washington 99336

Re: K162383
Trade/Device Name: Cadwell Sierra Summit, Cadwell Sierra Ascent
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic Electromyograph
Regulatory Class: Class II
Product Code: IKN, GWF, JXE, GWJ, GWE, GZP
Dated: January 19, 2017
Received: January 23, 2017

Dear Christopher Bolkan:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162383

Device Name
Cadwell Sierra Summit, Cadwell Sierra Ascent

Indications for Use *(Describe)*

Cadwell Sierra Summit:
Cadwell Sierra Summit is indicated for acquisition, display, storage, transmission, analysis, and reporting of electrophysiological and environmental data including Electromyography (EMG), Nerve Conduction Studies (NCS), Evoked Potentials (EP), and Autonomic Reponses (RR Interval Variability). The Cadwell Sierra Summit is used to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the peripheral nerve; Electromyography measures the electrical activity of the muscle, and Evoked Potentials measure the electrical activity from the central nervous system. The interface for third-party non-invasive imaging display and control is used to visualize the morphology and location of nerves and muscles, and serves as an aid in confirming the results of the aforementioned modalities.

Cadwell Sierra Summit is indicated for use by qualified medical practitioners. This device does not provide any diagnostic conclusion about the patient's condition to the user.

Cadwell Sierra Ascent:
Cadwell Sierra Ascent is indicated for acquisition, display, storage, transmission, analysis, and reporting of electrophysiological and environmental data including Electromyography (EMG), Nerve Conduction Studies (NCS), and Somatosensory Evoked Potentials (SEP). The Cadwell Sierra Ascent is used to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions.

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

Cadwell Sierra Ascent is indicated for use by qualified medical practitioners. This device does not provide any diagnostic conclusion about the patient's condition to the user.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Cadwell Sierra Summit and Ascent

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

1. Submitter / 510(k) Holder:

Name	Cadwell Industries, Inc.
Address	909 N. Kellogg Street, Kennewick, Washington 99336
Establishment Reg No.	3020018
Contact person	Mr. Chris Bolkan
Phone number	509-735-6481
Fax number	509-783-6503
Email	ChrisB@Cadwell.com
Date Prepared	August 5, 2016

2. Device Name:

Proprietary name	Cadwell Sierra Summit, Cadwell Sierra Ascent
Common name	Diagnostic Electromyograph
Device Class	Class II
Classification name	Electromyograph, Diagnostic Stimulator, Electrical, Evoked Response Device, Nerve Conduction Velocity Measurement Stimulator, Auditory, Evoked Response Stimulator, Photic, Evoked Response Stimulator, Mechanical, Evoked Response
Product Code, Regulation	IKN 21 CFR 890.1375 GWF 21 CFR 882.1870 JXE 21 CFR 882.1550 GWJ 21 CFR 882.1900 GWE 21 CFR 882.1890 GZP 21 CFR 882.1880

3. Predicate Devices:	510(k) Number	Device Name
Primary Predicate	K112052	Carefusion Nicolet EDX with Viking Software
Reference Predicates	K971214	Cadwell Kilowin (Easy II EEG, Sierra II EMG/EP, Cascade IOM)

4. Device Description:

The Cadwell Sierra Summit and Ascent systems are designed for the acquisition, display, analysis, storage, and reporting of electrophysiologic information from the human nervous and muscular systems. The systems are designed to perform nerve conduction studies (NCS), needle electromyography (EMG) studies and evoked potential (EP) studies. The Sierra Summit is the full featured version and also includes autonomic (RR Interval) studies and an interface to allow display and control of non-invasive third-party imaging modalities.. Hereafter, the Sierra Summit is described as the full featured variant. The Summary of Technical Characteristics table below details the differences between the Summit and Ascent systems.

The Sierra Summit provides a variety of test protocols spanning the various test modalities above.

The Cadwell Sierra Summit consists of the following major components:

- Sierra Summit console base unit with integrated control panel
- Amplifier (available in two types: 2 channel with two non-switched differential channels, or a 12 channel with 4 non-switched differential and 8 switched referential channels. The number of available channels is controlled by a software license)
- Laptop or Desktop computer (Windows OS) with keyboard and mouse
- Display monitor
- Summit software

The Sierra Summit has the following optional accessories/components:

- Remote Head Box (for 3-12 channel amplifier)
- StimTroller (Hand Held Electrical Stimulator)
- Electrical Stimulator Switch Box
- Footswitch (single)
- Visual Stimulators (LED Goggles, LCD Checks)
- VEP Calibration Sensor
- Headphones or other auditory transducers
- Reflex Hammer
- Temperature Probe
- Cart
- Isolation Transformer or Medical Grade Power Strip
- Printer

5. Indications for Use

Sierra Summit:

Cadwell Sierra Summit is indicated for acquisition, display, storage, transmission, analysis, and reporting of electrophysiological and environmental data including Electromyography (EMG), Nerve Conduction Studies (NCS), Evoked Potentials (EP), and Autonomic Reponses (RR Interval Variability). The Cadwell Sierra Summit is used to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the peripheral nerve; Electromyography measures the electrical activity of the muscle, and Evoked Potentials measure the electrical activity from the central nervous system. The interface for third-party non-invasive imaging display and control is used to visualize the morphology and location of nerves and muscles, and serves as an aid in confirming the results of the aforementioned modalities.

Cadwell Sierra Summit is indicated for use by qualified medical practitioners. This device does not provide any diagnostic conclusion about the patient's condition to the user.

Sierra Ascent:

Cadwell Sierra Ascent is indicated for acquisition, display, storage, transmission, analysis, and reporting of electrophysiological and environmental data including Electromyography (EMG), Nerve Conduction Studies (NCS), and Somatosensory Evoked Potentials (SEP). The Cadwell Sierra Ascent is used to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions.

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

Cadwell Sierra Ascent is indicated for use by qualified medical practitioners. This device does not provide any diagnostic conclusion about the patient's condition to the user.

6. Summary of Technical Characteristics Compared to the Predicate Devices

The Cadwell Sierra Summit and Ascent are substantially equivalent to predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate device through comparison in areas that include intended use, design, functionality, principle of operation, specifications, material composition, and performance.

1. General				
	This Submission	This Submission	Reference Predicate	Primary Predicate

Characteristics	Cadwell Sierra Summit	Cadwell Sierra Ascent (variant of Summit)	Cadwell Kilowin (Sierra II EMG/EP) (K971214)	Carefusion Nicolet EDX with Viking Software (K112052)
1.1 Indications for Use	Cadwell Sierra Summit is indicated for acquisition, display, storage, transmission, analysis, and reporting of electrophysiological and environmental data including Electromyography (EMG), Nerve Conduction Studies (NCS), Evoked Potentials (EP), and Autonomic Reponses (RR Interval Variability). The Cadwell Sierra Summit is used as an aid in the location of neural structures or muscle, to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the peripheral nerve; Electromyography measures the electrical activity of the muscle, and Evoked Potentials measure the electrical activity from the central nervous system. The interface for third-party non-invasive imaging display and control is	Cadwell Sierra Ascent is indicated for acquisition, display, storage, transmission, analysis, and reporting of electrophysiological and environmental data including Electromyography (EMG), Nerve Conduction Studies (NCS), and Somatosensory Evoked Potentials (SEP). The Cadwell Sierra Ascent is used as an aid in the location of neural structures or muscle, to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the peripheral nerve; Electromyography measures the electrical activity of the muscle, and Evoked Potentials measure the electrical activity from the central nervous system. Cadwell Sierra Ascent is indicated for use by qualified medical practitioners. This device does not provide any diagnostic conclusion about the	Kilowin is an electrodiagnostic device designed to measure and display the electrical signals generated by peripheral nerve, muscle, and central nervous system. It will acquire the data necessary for electroencephalography (EEG), electronystagmography (ENG), electrocardiology (ECG), electromyography (EMG), nerve conduction velocity (NCV, F Wave, and H reflex), evoked potentials (EP, brainstem, visual, somatosensory), repetitive nerve stimulation and sleep assessment. The Kilowin instrument is designed for use during the duration of the procedure only. Use of the proposed device is to be administered under the direction of a trained physician, surgeon, neurologist, or electrophysiologist in the operating room or clinic. The Kilowin device(s) are intended for use during	The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiologic 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 Potentials (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP). The Nicolet EDX with Viking Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The listed modalities do include overlap in

	used to visualize the morphology and location of nerves and muscles, and serves as an aid in confirming the results of the aforementioned modalities. Cadwell Sierra Summit is indicated for use by qualified medical practitioners. This device does not provide any diagnostic conclusion about the patient's condition to the user.	patient's condition to the user.	electroencephalography (EEG), electronystagmography (ENG), electromyography (EMG), nerve conduction velocity (NCV, F wave, and H reflex), evoked potentials (brainstem, visual, somatosensory) repetitive nerve stimulation testing and sleep assessment.	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.
1.2 Warnings	Items related to off-label use or misuse.	Items related to off-label use or misuse.	Items related to off-label use or misuse.	Items related to off-label use or misuse.
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.	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.
2. General Design				
2.1 General Systems Approach	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.

2.2 User Input Device	Windows mouse/keyboard driven graphic interface with dedicated control panel.	Windows mouse/keyboard driven graphic interface with dedicated control panel.	Windows mouse/keyboard driven graphic interface with dedicated control panel.	Windows mouse/keyboard driven graphic interface with dedicated control panel.
2.3 User Output Device	Digital color display and commercial printers.	Digital color display and commercial printers.	Digital color display and commercial printers.	Digital color display and commercial printers.
2.4 Patient Inputs	1 to 12 channel amplifier, isolated.	2 channel amplifier, isolated.	2 or 4 channel amplifier, isolated.	2 to 8 channel amplifier, isolated.
2.5 Signal Acquisition	Analog to digital conversion at 100 kHz (EMG channels), 25 kHz (EP channels).	Analog to digital conversion at 100 kHz.	Analog to digital conversion at 76.8 kHz (2 channel), 38.4 kHz (4 channel).	Analog to digital conversion at 48kHz sample rate
2.6 Trigger Input (synchronization to external events).	Yes (4)	Yes (2)	No	Yes (2)
2.7 Trigger Output (synchronization for external devices)	Yes (4)	Yes (2)	Yes (1)	Yes (2)
2.8 Footswitch for hands-free operation	Yes	Yes	Yes	Yes
2.9 Use of standard software platform (Operating System)	Yes, Microsoft Windows	Yes, Microsoft Windows	Yes, Microsoft Windows	Yes, Microsoft Windows
2.10 Customization of protocols	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings
2.11 Application flexibility / expandability	Via software update	Via software update	Via software update	Via software update
2.12 Safety Standards	U.S. and Canada: • UL60601-1:2006 • CSA C22.2#601.1 • ANSI/AAMI ES60601-1:2006 • CSA C22.2#60601-1:2008 CB Scheme:	U.S. and Canada: • UL60601-1:2006 • CSA C22.2#601.1 • ANSI/AAMI ES60601-1:2006 • CSA C22.2#60601-1:2008 CB Scheme:	UL60601 CSA601-1 EN60601-1 (safety) EN60601-1-1 (medical systems) EN60601-2-40 (EMG/EP equipment)	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

	• IEC60601-1:2005 Ed.3 • EN60601-1-2:2007 • EN ISO14971:2012 • IEC60601-1-6:2010 • IEC 62366:2007 60601-1 Ed2: • IEC60601-1 Ed.2 • IEC60601-2-40:1998 EMC: • IEC60601-1-2:2007 • EN60601-1-2:2007 • FCC Part 15 Subpart B Section 15.107 & 15.109 LED Goggles light output: • ISO 15004 European Community • CE Mark 0344 Quality Management System • EN ISO 13485:2012	• IEC60601-1:2005 Ed.3 • EN60601-1-2:2007 • EN ISO14971:2012 • IEC60601-1-6:2010 • IEC 62366:2007 60601-1 Ed2: • IEC60601-1 Ed.2 • IEC60601-2-40:1998 EMC: • IEC60601-1-2:2007 • EN60601-1-2:2007 • FCC Part 15 Subpart B Section 15.107 & 15.109 European Community • CE Mark 0344 Quality Management System • EN ISO 13485:2012	EN60601-1-1-2 (EMC) ISO 13485 (quality system)	ED1 Rev:2003/06/30 CAN/CSA-C22.2 no. 601-1-M90 Issue:1990/01/01 Rev:2003/11 European Community (CE Mark)
2.13 Patient circuitry isolation	Optic/transformer	Optic/transformer	Optic/transformer	Optic/transformer

2.14 System Components	Summit base console including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface, Control Panel, USB Hub, dual speakers; 1-2 Ch. Amplifier; 3-12 Ch. Amplifier; Computer, monitor, keyboard, mouse, printer;	Ascent base console including 1 electrical stimulator, trigger input/output, Control Panel, USB Hub, dual speakers; 2 Ch. Amplifier; Computer, monitor, keyboard, mouse, printer;	Kilowin base console including 1 electrical stimulator, auditory and visual stimulator, trigger output, LED goggle interface, Control Panel, Ethernet port, single speaker. 2 Ch. Amplifier 4 Ch. 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;
2.15 System computer interface	USB	USB	Ethernet (RJ-45)	USB
2.16 System power supply	Mains (100-240 VAC) thru an isolation transformer depending on system configuration	Mains (100-240 VAC) thru an isolation transformer depending on system configuration	Mains (100-240 VAC) thru an isolation transformer depending on system	Mains (100-240 VAC) thru an isolation transformer
2.17 Amplifier power supply	12 VDC from base console	12 VDC from base console	12 VDC from base console	15 VDC from base console
2.18 Size (L/W/D) cm	37.6 x 38.1 x 6.4 (base console)	37.6 x 38.1 x 6.4 (base console)		35.6 x 34.3 x 8.6 (base console)
2.19 Weight kg	3.4 (base console)	3.4 (base console)		3.5 (base console)
3. Design – Acquisition				
3.1 Number of channels	1 to 12	2	2 or 4	2 to 8
3.2 CMRR	>115 dB	>115 dB	>115 dB	>110 dB
3.3 Noise	<0.6 uV RMS	<0.6 uV RMS	<2 uV RMS	<0.6uV RMS (from 2Hz to 10kHz)
3.4 Input Impedance	>1000 MΩ	>1000 MΩ	>1000 MΩ	>1000 MΩ
3.5 Low Filter	0.3 Hz to 2 kHz	0.3 Hz to 2 kHz	0.04 Hz to 2 kHz	0.05 Hz to 5 kHz
3.6 High Filter	30 Hz to 20 kHz	30 Hz to 20 kHz	30 Hz to 10 kHz	30 Hz to 20 kHz
3.7 Notch Filter	50/60 selectable	50/60 selectable	50/60 selectable	50/60 selectable
3.8 A/D conversion	16 bit	16 bit	16 bit	24 bit
3.9 Sampling rate (cumulative)	600 kHz	200 kHz	153.6 kHz	384 kHz
3.10 Time base range	0.1 to 10,000 ms	0.1 to 10,000 ms	0.1 to 10,000 ms	0.01 to 5000 ms
3.11 Number of Time bases allowed	Single	Single	Single	Multiple

3.12 Trigger mode	Free-run, internal, external	Free-run, internal, external	Free-run, external	Free-run, internal, external
3.13 Signal delay (pre/post)	-9 to +9 divisions, depending on time base	-9 to +9 divisions, depending on time base	-9 to +9 divisions, depending on time base	-3000 to +500 ms
3.14 Impedance meter	0.1Ω to 100 kΩ	0.1Ω to 100 kΩ	0.1Ω to 100 kΩ	500Ω to 480kΩ
4. Design – Stimulators				
4.1 Electrical Stimulator				
4.1.1 Type	Constant Current	Constant Current	Constant Current	Constant Current or Constant Voltage
4.1.2 Number	1 or 2	1	1	1 or 2
4.1.3 Maximum Output	100mA or 400V	100mA or 400V	100mA or 400V	100mA or 400V
4.1.4 Duration	0.05 to 1 ms	0.05 to 1 ms	0.05 to 1 ms	0.01 to 1 ms
4.1.5 Mode	Single or Train	Single or Train	Single or Train	Single or Train
4.1.6 Biphasic	Yes	Yes	No	Yes
4.2 Auditory Stimulator				
4.2.1 Type	Click, Pip, Burst	N/A	Click, Pip, Burst	Click, Pip, Burst
4.2.2 Intensity	0 to 140 dB pSPL	N/A	0 to 128 dB pSPL	0 to 139 dB pSPL
4.2.3 Polarity	Condensation, Rarefaction, Alternating	N/A	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating
4.2.4 Tone Frequency	250 to 8000 Hz	N/A	250 to 8000 Hz	250 to 8000 Hz
4.2.5 Click Duration	0.05 to 1 ms	N/A	0.1 ms	0.05 to 1 ms
4.2.6 Side	Left, Right, Both	N/A	Left, Right, Both	Left, Right, Both
4.2.7 Transducers	TDH 39, Inserts, Bone Vibrator	N/A	TDH 39, Inserts, Bone Vibrator	TDH 39, TIP 300, Bone Vibrator
4.3 Visual Stimulator				
4.3.1 Type	LCD Checks, LED Goggles	N/A	CRT Checks, LED Goggles	CRT Checks, LED Goggles
4.3.2 Latency Delay Calibrator (for LCD Checks)	Yes	N/A	N/A	N/A
5. EMG Application Modules				
5.1 Free Run Acquisition	Yes	Yes	Yes	Yes
5.2 Nerve Conduction Study (NCS)	Yes	Yes	Yes	Yes

5.3 Stimulator Triggered	Yes	Yes	Yes	Yes
5.4 Signal Triggered Acquisition	Yes	Yes	Yes	Yes
5.5 Spontaneous Activity (SPA)	Yes	Yes	Yes	Yes
5.6 Single Fiber EMG (SFEMG)	Yes	No	Yes	Yes
5.7 Motor Unit Analysis	Yes	Yes	Yes	Yes
5.8 F-Wave	Yes	Yes	Yes	Yes
5.9 H Reflex	Yes	Yes	Yes	Yes
5.10 Sympathetic Skin Response (SSR)	Yes	Yes	Yes	Yes
5.11 RR Interval Variability	Yes	No	Yes	Yes
5.12 Repetitive Nerve Stim	Yes	Yes	Yes	Yes
6. Evoked Potential Application Modules				
6.1 Somatosensory EP (SEP)	Yes	Yes	Yes	Yes
6.2 Auditory EP (AEP)	Yes	No	Yes	Yes
6.3 Visual EP (VEP)	Yes	No	Yes	Yes
6.4 P300	Yes	No	Yes	Yes
7. Other Application Modules				
7.1 Multi-modality IONM	No	No	No	Yes
7.2 EEG	No	No	No	Yes
7.3 ENG	No	No	No	Yes
7.4 ECG	No	No	No	No
7.5 Sleep (PSG)	No	No	No	No
8. Image Display and Control Interface				
8.1 Display and control of non-invasive third-party imaging modality (example: Ultrasound)	Yes Integrated (concurrent) ultrasound display and control using the Telemed Ultrasound System (K113184) with Echo Wave II software.	No	No	No Supports ultrasound by running a third-party scanner in a non-integrated, non-concurrent format (launched separately from desktop). Interson USB Ultrasound Probe System, K070907.

7. Summary of Performance Testing

Biocompatibility:
The Sierra Summit and Ascent have no patient contact materials, and therefore this section does not apply.

The hand-held StimTroller, LED Goggles, and accessories for use with the Sierra Summit and Ascent have patient contact materials and are made from medical grade biocompatible materials.

The appropriate component materials for these accessories were verified to be biocompatibility in accordance with the following standard:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Verification results indicate that the appropriate component materials comply with the standard.

Software:
The Cadwell Sierra Summit and Ascent software contains MODERATE level of concern software. Software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with internal requirements and the following guidance documents:

- *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.*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *FDA guidance: Content of premarket submissions for management of cybersecurity in medical devices, 02 Oct 14.*
- *IEC 62304: 2006, Medical device software - Software life cycle processes*

Test results indicate that the software complies with its predetermined specifications and the applicable guidance documents.

Electrical Safety:
The Sierra Summit was tested as worst case for safety and essential performance in accordance with the following standard(s):

- *ANSI/AAMI ES60601-1: 2005/(R)2012, A1:2012, C1:2009/(R)2012, A2:2010/(R)2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*
- *IEC 60529: 1989, Am1: 1999, Am2: 2013, Cor2: 2015, Degrees of protection provided by enclosures (IP Code).*

Test results indicate that the Sierra Summit and Ascent comply with the applicable standards.

Electromagnetic Compatibility:
The Sierra Summit was tested as worst case in accordance with the following standard:

- *IEC 60601-1-2: 2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.*

Test results indicate that the Sierra Summit and Ascent comply with the applicable standards.

Performance Testing – Bench:
The Sierra Summit was tested as worst case for performance in accordance with internal requirements and the following standards:

- *IEC 60068-2-27: 2008, Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock*
- *IEC 60068-2-64: 2008, Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance*
- *IEC 60601-2-40: 1998, Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment*
- *IEC 60601-1-6: 2010, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*
- *MIL-STD-810E, Environmental Test Methods and Engineering Guidelines*
- *ISTA Procedure 2a, Partial simulation performance test procedure – Packaged-products 150 lb (68 kg) or less.*

Test results indicate that the Sierra Summit and Ascent comply with the predetermined specifications and the applicable standards.

8. Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the Sierra Summit and Ascent. The results of these activities demonstrate that the Summit and Ascent are as safe, effective, and performance is substantially equivalent to the predicate devices.