August 17, 2023

Cadwell Industries, Inc.
Jason Ford
Regulatory Affairs Manager
909 North Kellogg Street
Kennewick, Washington 99336

Re: K230415
Trade/Device Name: Cadwell Guardian
Regulation Number: 21 CFR §882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF, ETN, GWE, GWJ, GWQ, GZO, IKN, JXE, OLT, PDQ
Dated: July 20, 2023
Received: July 21, 2023

Dear Jason Ford:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Patrick Antkowiak
-S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Cadwell Guardian

Indications for Use *(Describe)*

The Guardian with Cascade Surgical Studio software is an electroneurodiagnostic device that acquires, displays, and stores physiologic data from peripheral sensory and motor nerves, muscles, and the central nervous system, generated either spontaneously or elicited by stimuli.

Guardian can perform somatosensory, auditory, and visual evoked potentials (EPs), electroencephalography (EEG), electrocorticography (ECoG), spontaneous and triggered electromyography (EMG), transcranial motor evoked potentials (TcMEP), direct cortical stimulation (DCS), direct nerve stimulation (TEMG, DNS), nerve conduction studies (NCS), and Train of Four (TOF) analysis.

Guardian can provide remote review outside of the operating room.

Guardian is used by or under the direction of a licensed physician, surgeon, or neurologist in a professional healthcare facility environment for pre-operative, intraoperative and post-operative testing.

The following functions are specifically supported individually or in combination:

Evoked Potentials (EPs): Guardian can provide electrical, auditory, and visual stimulation and measure, display, record, and store the electrical activity of the nervous system in response to the stimulations delivered.

Electroencephalography (EEG): Guardian can measure, display, record, and store electrical activity of the brain from two or more electrodes on the scalp.

Electrocorticography (ECoG): Guardian can measure, display, record, and store electrical activity directly from the brain using two or more electrodes.

Free Run Electromyography (EMG): Guardian can acquire, display, record, and store EMG activity of motor nerves.

Triggered Electromyography (TEMG): Guardian can electrically stimulate motor nerves, and display, record, and store the results.

Transcranial Motor Evoked Potentials (TcMEP): Guardian can deliver electrical transcranial stimulation, and display, record, and store the results.

Direct Cortical Stimulation (DCS): Guardian can deliver electrical stimulation to various areas of the cerebral cortex, and display, record, and store the results.

Direct Nerve Stimulation (DNS): Guardian can electrically stimulate cranial and peripheral nerves, and display, record, and store the results.

Nerve Conduction Study (NCS): Guardian can measure, display, record, and store sensory and motor nerve conduction time (latency) by applying a stimulus to peripheral nerves, the spinal cord, and the central nervous system.

Train of Four (TOF): Guardian can deliver a train of four pulses, and measure, display, record, and store the results.

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

Submitter:	Cadwell Industries, Inc. 909 N. Kellogg Street Kennewick, Washington 99336 509-735-6481
Contact Person:	Jason Ford Email: jasonf@cadwell.com
Date Prepared:	February 9, 2023
Trade Name:	Cadwell Guardian™
Regulation Name:	Evoked response stimulator
Regulation Number:	21 CFR §882.1870
Regulatory Classification:	Class II
Product Codes:	GWF, ETN, GWE, GWJ, GWQ, GZO, IKN, JXE, OLT, PDQ
Classification Panel:	Neurology
Primary Predicate Device:	Cadwell Industries, Inc. Cascade IOMAX™ Intraoperative Monitor Product Code: GWF, DQA, ETN, GWE, GWJ, GWQ, GZO, IKN, JXE, OLT, PDQ 510(k) Number: K162199
Secondary Predicate Device:	Inomed ISIS Headboxes and Neurostimulator Product Code: GWF, GWJ, GWQ, ETN, IKN 510(k) Number: K212166
Reference Predicate Devices:	Cadwell Industries, Inc. Cadwell Zenith System (K181466) Cadwell Industries, Inc. Sierra Summit (K162383) Nihon Kohden Neuromaster G1 Mee2000 (K142624)
Device Description:	The Cadwell Guardian is a multi-modality intraoperative neurophysiological monitoring system with up to 80 channels of data acquisition.

The Guardian system is designed to be flexible and scalable depending on customer and procedural requirements. All systems require a Power Comm and Guardian Base, which contains an electrical Transcranial Stimulator. The user may select up to two Omni Amplifiers, two ES-10 electrical stimulators, one AVX auditory and visual stimulator, and one SMX-32 EEG amplifier that contains a low current electrical stimulator, in order to meet specific requirements.

The Guardian requires a (PC) with Windows operating system. The Guardian system uses a new version (4.0) of previously cleared Cadwell Cascade Surgical Studio software. Surgical Studio acquires, stores and reviews a wide range of intraoperative neurophysiological data, such as EMG, EEG, SSEP, BAEP, VEP, MEP and TOF, and includes Report Generation.

Indications for Use:

The Guardian with Cascade Surgical Studio software is an electroneurodiagnostic device that acquires, displays, and stores physiologic data from peripheral sensory and motor nerves, muscles, and the central nervous system, generated either spontaneously or elicited by stimuli.

Guardian can perform somatosensory, auditory, and visual evoked potentials (EPs), electroencephalography (EEG), electrocorticography (ECoG), spontaneous and triggered electromyography (EMG), transcranial motor evoked potentials (TcMEP), direct cortical stimulation (DCS), direct nerve stimulation (TEMG, DNS), nerve conduction studies (NCS), and Train of Four (TOF) analysis.

Guardian can provide remote review outside of the operating room.

Guardian is used by or under the direction of a licensed physician, surgeon, or neurologist in a professional healthcare facility environment for pre-operative, intraoperative and post-operative testing.

The following functions are specifically supported individually or in combination:

Evoked Potentials (EPs): Guardian can provide electrical, auditory, and visual stimulation and measure, display, record, and store the electrical activity of the nervous system in response to the stimulations delivered.

Electroencephalography (EEG): Guardian can measure, display, record, and store electrical activity of the brain from two or more electrodes on the scalp.

Electrocorticography (ECoG): Guardian can measure, display, record, and store electrical activity directly from the brain using two or more electrodes.

Free Run Electromyography (EMG): Guardian can acquire, display, record, and store EMG activity of motor nerves.

Triggered Electromyography (TEMG): Guardian can electrically stimulate motor nerves, and display, record, and store the results.

Transcranial Motor Evoked Potentials (TcMEP): Guardian can deliver electrical transcranial stimulation, and display, record, and store the results.

Direct Cortical Stimulation (DCS): Guardian can deliver electrical stimulation to various areas of the cerebral cortex, and display, record, and store the results.

Direct Nerve Stimulation (DNS): Guardian can electrically stimulate cranial and peripheral nerves, and display, record, and store the results.

Nerve Conduction Study (NCS): Guardian can measure, display, record, and store sensory and motor nerve conduction time (latency) by applying a stimulus to peripheral nerves, the spinal cord, and the central nervous system.

Train of Four (TOF): Guardian can deliver a train of four pulses, and measure, display, record, and store the results.

Technology Comparison:

Characteristics	***Proposed Device Cadwell Guardian***	***Predicate Device Cadwell Cascade IOMAX (K162199)***	***Predicate Device Inomed ISIS (K212166)***	***Predicate Device Cadwell Zenith (K181466)***	***Discussion of Major Differences***
Indications for Use	The Guardian with Cascade Surgical Studio software is an electroneurodiagnostic device that acquires, displays, and stores physiologic data from peripheral sensory and motor nerves, muscles, and the central nervous system, generated either spontaneously or elicited by stimuli. Guardian can perform somatosensory, auditory, and visual evoked potentials (EPs), electroencephalography (EEG), electrocorticography (ECoG), spontaneous and triggered electromyography (EMG), transcranial motor evoked potentials (TcMEP), direct cortical stimulation (DCS), direct nerve stimulation (TEMG, DNS), nerve conduction studies (NCS), and Train of Four (TOF) analysis. Guardian can provide remote review outside of the operating room. Guardian is used by or under the direction of a licensed physician, surgeon, or neurologist in a professional	The Cascade IOMAX™ Intraoperative Monitor with Surgical Studio software (IOMAX) is an electroneurodiagnostic device that acquires, displays and stores physiologic data from peripheral sensory and motor nerves, muscles and the central nervous system, generated either spontaneously or elicited by well-defined stimuli. The acquired data are necessary to perform somatosensory, auditory and visual evoked potentials (EPs), electroencephalography (EEG), electromyography (EMG), transcranial motor evoked potentials (TcMEPs), direct cortical stimulation, nerve conduction studies and Train of Four (TOF) analysis. SpO_2 measures and displays oxygen saturation and heart rate information. The system also delivers direct nerve stimulation required for specific surgical procedures. Evoked Potentials (EPs): IOMAX provides electrical, auditory or visual stimulation and measures, displays, records, and stores the electrical activity of the	ISIS Headbox 5042XX: The products are intended for intraoperative neuromonitoring; for the recording of electrophysiological signals and stimulating nerve and muscle tissues. The products are intended for use in the operating room to measure and display the electrical signals generated by muscle, peripheral nerves, and the central nervous system. The products support the clinical application of Electroencephalography (EEG), Electromyography (EMG), Somatosensory Evoked Potentials (SEP), Motor Evoked Potentials (MEP), and Auditory Evoked Potentials (AEP). The products are not intended for monitoring life-sustaining functions. ISIS Neurostimulator 504180: The ISIS Neurostimulator is intended for the provision of neurophysiological stimulation when used in surgical procedures and for diagnostics. It is suitable for	The Cadwell Zenith is an electroneurodiagnostic device that accepts, measures, displays, records, and stores electrical activity of the brain via scalp and intracranial electroencephalography (EEG) signals, and, utilizing an integrated switch matrix, relays stimulation signals to the patient. It can obtain, display and store electrophysiological data from the central nervous system, generated either spontaneously or elicited by well-defined stimuli. The data is used to perform neurodiagnostic evaluations, including EEG and direct cortical stimulation. Zenith is used with Cadwell acquisition software. Zenith is used by or under the direction of a licensed physician, surgeon, or neurologist in a professional healthcare facility environment for pre-operative, intraoperative	The indications for use between the proposed device and the predicates have no substantive differences. The proposed device does not include SpO2 because this measurement is not a customer requirement. The proposed device describes the use of ECoG, which was previously described in general terms under EEG in the predicate device IFU. EEG and ECoG are listed separately to differentiate between direct brain recording and scalp recording, however both are recordings obtained from 2 or more electrodes attached to the patient head, as described in the predicate device IFU. These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.

Characteristics	*Proposed Device Cadwell Guardian*	*Predicate Device Cadwell Cascade IOMAX (K162199)*	*Predicate Device Inomed ISIS (K212166)*	*Predicate Device Cadwell Zenith (K181466)*	*Discussion of Major Differences*
	healthcare facility environment for pre-operative, intraoperative and post-operative testing. The following functions are specifically supported individually or in combination: Evoked Potentials (EPs): Guardian can provide electrical, auditory, and visual stimulation and measure, display, record, and store the electrical activity of the nervous system in response to the stimulations delivered. Electroencephalography (EEG): Guardian can measure, display, record, and store electrical activity of the brain from two or more electrodes on the scalp. Electrocorticography (ECoG): Guardian can measure, display, record, and store electrical activity directly from the brain using two or more electrodes. Free Run Electromyography (EMG): Guardian can acquire, display, record, and store EMG activity of motor nerves. Triggered Electromyography (TEMG): Guardian can electrically stimulate motor nerves, and display, record, and store the results.	nervous system in response to the stimulation. EEG: IOMAX measures, displays, records, and stores electrical activity of the brain from two or more electrodes on the head. Free Run EMG: IOMAX acquires, displays, records, and stores spontaneous EMG activity of motor nerves by continually displaying a live stream of mechanically induced myotome contractions. Triggered EMG (TEMG): IOMAX electrically stimulates the motor nerves, and displays, records, and stores the resulting compound muscle action potentials in the innervated muscle. TcMEP: IOMAX delivers transcranial stimulation via dedicated outputs for intraoperative assessment. Cortical Stimulation: IOMAX delivers Low Current Stimulation (LCS) during surgical procedures to map various areas of the cortex. Nerve Conduction Study (NCS): IOMAX measures, displays, records, and stores sensory and motor nerve conduction time (latency) by applying a stimulus to	continuous operation and can be used in the following fields: Transcranial electrical stimulation (TES) Direct cortical stimulation (DCS) Direct nerve stimulation (DNS) Transcutaneous electrical nerve stimulation (TNS) Direct muscle stimulation (DMS)	and post-operative testing on patients of all ages.	

Characteristics	*Proposed Device Cadwell Guardian*	*Predicate Device Cadwell Cascade IOMAX (K162199)*	*Predicate Device Inomed ISIS (K212166)*	*Predicate Device Cadwell Zenith (K181466)*	*Discussion of Major Differences*
	Transcranial Motor Evoked Potentials (TcMEP): Guardian can deliver electrical transcranial stimulation, and display, record, and store the results. Direct Cortical Stimulation (DCS): Guardian can deliver electrical stimulation to various areas of the cerebral cortex, and display, record, and store the results. Direct Nerve Stimulation (DNS): Guardian can electrically stimulate cranial and peripheral nerves, and display, record, and store the results. Nerve Conduction Study (NCS): Guardian can measure, display, record, and store sensory and motor nerve conduction time (latency) by applying a stimulus to peripheral nerves, the spinal cord, and the central nervous system. Train of Four (TOF): Guardian can deliver a train of four pulses, and measure, display, record, and store the results.	peripheral nerves, the spinal cord, and the central nervous system. Train of Four (TOF) or Twitch Test: IOMAX delivers a train of four pulses and measures, displays, records, and stores the compound muscle action potential amplitude fade for analysis. SpO2: IOMAX measures and displays oxygen saturation and heart rate information Remote Reader: IOMAX provides passive, real time remote review of intraoperative monitoring for a physician outside of the operating room. IOMAX is used by or under the direction of a licensed physician, surgeon, or neurologist in a professional healthcare facility environment for pre-operative, intraoperative and post-operative testing.			
Population	Age: Newborn to geriatric Weight: > 2.5 kg	Age: Newborn to geriatric Weight: > 2.5 kg	None stated.	Patients of all ages.	No significant difference.
Modalities	Evoked potential (EP) in the form of: ● Brainstem auditory	Evoked potential (EP) in the form of: ● Brainstem auditory	EEG, EMG, SEP, MEP, AEP, TES, DCS, DNS, TNS, DMS	Electroencephalogram (EEG) External cortical	Guardian does not include SpO_2. These differences in the proposed device do not raise new questions of safety or

Characteristics	*Proposed Device* *Cadwell Guardian*	*Predicate Device* *Cadwell Cascade IOMAX (K162199)*	*Predicate Device* *Inomed ISIS (K212166)*	*Predicate Device* *Cadwell Zenith (K181466)*	*Discussion of Major Differences*
	• Visual • Somatosensory Transcranial electrical motor evoked potential (TcMEP) Electromyography (EMG) Electroencephalogram (EEG) Electrocorticography (EcoG) Nerve conduction studies (NCS) including: • NCV • F wave • H reflex Train of four (TOF) Photic Stimulation Threshold mode Direct cortical stimulation Direct nerve stimulation	• Visual • Somatosensory Transcranial electrical motor evoked potential (TcMEP) Electromyography (EMG) Electroencephalogram (EEG) - Nerve conduction studies in the form of: • NCV • F wave • H reflex Train of four (TOF) SpO_2 and heart rate values Threshold mode Direct cortical Stimulation		stimulation Photic stimulation Video	effectiveness, and is therefore considered substantially equivalent.
System Configuration	Computer based equipment with dedicated hardware peripherals/ components, and custom acquisition software. USB cable connected from base unit to computer Modules interconnected via interconnect cables (ethernet, multi-pin)	Same	Same	Same	-

Characteristics	*Proposed Device* *Cadwell Guardian*	*Predicate Device* *Cadwell Cascade IOMAX (K162199)*	*Predicate Device* *Inomed ISIS (K212166)*	*Predicate Device* *Cadwell Zenith (K181466)*	*Discussion of Major Differences*
	Software installed and operated on computer				
System Components	One (1) **Power Comm** module providing device power and communication, and USB connection to PC. One (1) **Base Unit** containing the following: Up to two (2) removable 24 channel amplifiers, each with up to two (2) amplifier input extenders One (1) transcranial stimulator (TCS) with 9 multiplexed outputs, with one (1) TCS output extender Two (2) Trigger inputs Two (2) Trigger outputs Up to two (2) **ES-10** Stimulators, each containing 1 medium current stimulator (MCS) multiplexed to 8 output pairs, and 1 low current stimulator (LCS) multiplexed to 2 output pairs Up to one (1) **SMX-32** 32 channel EEG amplifier with one (1) integrated low current stimulator (LCS)	One (1) Power Comm module providing device power and communication, with Two (2) trigger inputs and Two (2) trigger outputs, and USB connection to PC. Up to one (1) Cortical Module, containing the following: One (1) 16 channel amplifier One (1) Stereo Auditory Stimulator with up to (1) Insert Earphones One (1) Stereo Visual Stimulator with up to (1) VEP Goggles One (1) transcranial stimulator (TCS) with 9 multiplexed outputs One (1) Low Current Stimulator (LCS) Up to four (4) Limb Modules, each containing the following: 8 multipurpose recording channels	Unspecified	IOMAX Cortical Module (acts as an external cortical stimulation source for the amplifier) Photic stimulator (connected to the personal computer (PC) upon which the acquisition hardware is deployed). Patient event button (connected to the IOMAX Base Module). Video recorders (connected to the PC or to the user's network).	Both the proposed device and the IOMAX predicate device have the same types of measurement functionality and the same types of stimulation functionality. Both contain the following: Power Comm Transcranial Stimulation (TCS) Medium Current Stimulation (MCS) Low Current Stimulation (LCS) Multiplexing of various electrical stimulators Multiple general-purpose Amplifiers Two (2) Trigger Inputs Two (2) Trigger Outputs Stereo Audio Stimulator Stereo Visual Stimulator VEP Goggles AEP Insert Earphones Guardian hardware does not have built-in SpO2 functionality. Guardian does have up to one (1) **SMX-32** EEG amplifier that can be compared to the amplifier in the reference predicate (**Zenith Amplifier**). These differences in the proposed device do not raise new questions of safety or

Characteristics	*Proposed Device Cadwell Guardian*	*Predicate Device Cadwell Cascade IOMAX (K162199)*	*Predicate Device Inomed ISIS (K212166)*	*Predicate Device Cadwell Zenith (K181466)*	*Discussion of Major Differences*
	Up to one (1) **AVX** device containing auditory stimulator and visual stimulator. Up to (1) VEP Glow Goggle. Up to (1) Insert Earphones OR Headphones. Up to four (4) Auxiliary Cables to connect **ES-10**, **SMX-32**, and/or **AVX** to the Base Unit	One (1) medium current stimulator (MCS) multiplexed to 5 output pairs. SpO2 monitor			effectiveness, and is therefore considered substantially equivalent.

Characteristics	*Proposed Device Cadwell Guardian*	*Predicate Device Cadwell Cascade IOMAX (K162199)*	*Discussion of Major Differences*
Auditory Stimulator			
Output Type	Earphones and head phones	Earphones	Earphones and headphones have the same acoustic specification. These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Stimulus Waveform	User defined clicks, tones, chirps, pips	Click	Similar to reference predicate device, Neuromaster G1 (K142624). These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.

Characteristics	***Proposed Device Cadwell Guardian***	***Predicate Device Cadwell Cascade IOMAX (K162199)***	***Discussion of Major Differences***
Presentation	Left, right, or both ears	Same	-
Stimulus Phase (Polarity)	Condensation (positive), Rarefaction (negative), alternating	Same	-
Stimulus Intensity	33 to 125 dB peak sound pressure level (SPL)	70 to 125 dB peak sound pressure level (SPL)	Maximum stimulation is same as IOMAX predicate. Stimulation intensities are within range of reference predicate device, Neuromaster G1 (0-135 dB SPL) (K142624). These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Contralateral White Noise Masking	Contralateral masking from 0-60 dB below stimulus level maximum of 100 dB SPL, or off	Same	-
Click Pulse Duration or Rate	Pulse duration: 0.1 mS Repetition rate: 0.1-100Hz depending on sweep speed and interleave setup	Pulse Duration: Same Repetition Rate: 0.1 to 40 Hz depending on sweep speed and interleave setup	Proposed device repetition rate is equivalent to reference predicate device, Sierra Summit (0.1-90Hz) (K162383). These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Tone Burst Frequency	250-10,000 Hz	Not applicable	Within in range of reference device Neuromaster G1 (50-10,000 Hz) (K142624). These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.

Characteristics	***Proposed Device Cadwell Guardian***	***Predicate Device Cadwell Cascade IOMAX (K162199)***	***Discussion of Major Differences***
Rise/Fall Time of Tone Burst	4-100 mS	Not applicable.	No difference from reference predicate device, Sierra Summit (4-100mS) (K162383). These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Visual Stimulators			
Stimulus Modes	LED Goggle: Flash, left, right, or bilateral presentation. Pattern Reversal	LED goggles: Flash, left, right, or bilateral presentation	Proposed device includes Pattern Reversal. No difference from reference predicate device, Neuromaster G1 (K142624) These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Patterns	Checkerboard	Not applicable.	No difference from reference predicate device, Neuromaster G1 (K142624). These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Number of Horizontal Divisions	4, 8, 16, 32, 64, 128	Not applicable.	No difference from reference predicate device, Neuromaster G1 (4, 8, 16, 32, 64, 128) (K142624). These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
LED Flash Pulse Duration or Rate	Pulse duration up to 5mS	Same	-
Computer Hardware			
Type	PC	Same	-

Characteristics	***Proposed Device Cadwell Guardian***	***Predicate Device Cadwell Cascade IOMAX (K162199)***	***Discussion of Major Differences***
Memory	8 GB	Same	-
Network	10/100/1,000 Mb/s Ethernet	Same	-
CPU	Minimum: Dual Core i7, 3.0 GHz or faster Recommend Quad Core i7	Same	-
Storage Capacity	128+ GB	Same	-
Display			
Number of Waveform Traces	Unlimited	Same	-
Specific Waveform Display Modes	EP: Averaged, Live, Waterfall, Cursor Trends EEG: Default, Horizontal, Vertical, CSA, DSA EMG: Default, Horizontal, Vertical, Waterfall TOF: Vertical, Horizontal, Histogram, Table MEP: Default, Waterfall, Cursor Trend	Same	-
Cursors	Unlimited	Same	-
Display Scale	0.1 - 100,000 uV/Div 1 - 1,000 ms/Div	Same	-

Characteristics	***Proposed Device Cadwell Guardian***	***Predicate Device Cadwell Cascade IOMAX (K162199)***	***Discussion of Major Differences***
Computer Software			
Operating System	Windows 10 or 11	Windows® 7 or 10 Professional 64-bit	No significant difference. These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Application Software	Cadwell Surgical Studio 4.0 or higher	Cadwell Surgical Studio 3.2 or higher	
Physical Dimensions			
Power Comm	7.1 in x 5.8 in x 2.1 in (18.0x14.8x5.3 cm) Weight: 1.65 lb (0.75 kg)	6.5 in x 5.2 in x 2.8 in (16.5 x 13.3 x 7.1 cm) Weight: 2.0 Lbs (0.9 kg)	The proposed device dimension and weight are similar. These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.

Characteristics	***Proposed Device Cadwell Guardian***	***Predicate Device Cadwell Cascade IOMAX (K162199)***	***Discussion of Major Differences***
Major System Components	Base Module: 12 in x 15.3 in x 3 in (30.5 x 38.9 x 7.6 cm) Weight: 6.0 lbs (2.7 kg) SMX-32: 6.8 in x 5.3 in x 2.0 in (17.3 x 13.5 x 5.1 cm) Weight: 1.15 lb (0.52 kg) ES-10: 6.8 in x 5.3 in x 2.0 in (17.3 x 13.5 x 5.1 cm) Weight: 1.15 lb (0.52 kg) AVX: 6.8 in x 5.3 in x 2.0 in (17.3 x 13.5 x 5.1 cm) Weight: 1.15 lb (0.52 kg)	Cortical Module: 253 mm x 215 mm x 60 mm (10.0 in x 8.5 in x 2.4 in) Weight: 2.7 kg (6.0 lbs) Limb Module: 253 mm x 122 mm x 60 mm (10.0 in x 4.8 in x 2.4 in) Weight: 1.5 kg (3.4 lbs)	The proposed device dimensions and weights are similar. These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Electrical Power			
AC Mains	Power Comm: 100-240 VAC	Same	-
Frequency	Power Comm: 50 to 60 Hz	Same	-
Environmental			
Operating Temperature	All modules: 10 to 40 °C (50 to 104 °F)	All Modules: 10 to 35 °C (50 to 95 °F)	These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Operating Humidity	All modules: 20 to 95%, non-condensing	All Modules: 30 to 95 %, non-condensing	These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Operating Pressure	All modules: 700 to 1060 hPa	All Modules: Same	-

Characteristics	***Proposed Device Cadwell Guardian***	***Predicate Device Cadwell Cascade IOMAX (K162199)***	***Discussion of Major Differences***
Storage Temperature	All modules: -20C (-40F) to 65C (149F)	All Modules: Same	-
Storage Humidity	All modules: 5% to 95%, non-condensing	All Modules: 10 to 95 %, non-condensing	These differences in the proposed device do not raise new questions of safety or effectiveness, and is therefore considered substantially equivalent.
Storage Pressure	All modules: 500 to 1060 hPa	All Modules: Same	-

Electrical Safety:

The Cadwell Guardian was tested for safety and essential performance in accordance with the following safety standards:

- ES60601-1:2005+A1:2012
- IEC 60601-1-6:2010+A1:2013
- IEC 62304: 2006+A1:2015
- IEC 80601-2-26:2019
- IEC 60601-2-40:2016

Test results indicate that the Cadwell Guardian complies with the applicable standards.

Electromagnetic Disturbances:

The Cadwell Guardian was tested for performance in accordance with the following standards:

- IEC 60601-1-2:2014 + A1:2020

Test results indicate that the Cadwell Guardian complies with the applicable standards.

Performance Testing:

The Cadwell Guardian was tested in accordance with internal software requirements, system requirements, and usability requirements. Test results indicate that the Cadwell Guardian complies with its predetermined specifications.

Conclusion:

Verification and validation activities were conducted to establish the performance and safety characteristics of the Cadwell Guardian. The results of these activities demonstrate that the Cadwell Guardian is as safe, as effective, and performs as well as the predicate devices.

Therefore, the Cadwell Guardian is considered substantially equivalent to the predicate devices.