September 1, 2018

Cadwell Industries, Inc.
John Cadwell Jr
Senior Vice President
909 North Kellogg Street
Kennewick, Washington 99336

Re: K181466
Trade/Device Name: Cadwell Zenith System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GYC, GWF, ETN
Dated: June 1, 2018
Received: June 4, 2018

Dear John Cadwell Jr:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181466

Device Name
Cadwell Zenith System

Indications for Use *(Describe)*
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 and post-operative testing on patients of all ages.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submission Date:	01 June 2018
Submitter:	Cadwell Industries, Inc. 909 North Kellogg Street Kennewick, WA 99336
Submitter and Application Correspondent	Mr. John Cadwell Jr. Phone: +1 (800) 245-3001, Extension 222 Email: johnjr@cadwell.com
Manufacturing Site:	Cadwell Industries, Inc. 909 North Kellogg Street Kennewick, WA 99336
Trade Name:	Cadwell Zenith System
Common and Classification Name:	Electroencephalograph
Primary Classification Regulation:	21 CFR §882.1400
Primary Product Code:	GWQ
Secondary Product Codes:	GYC, GWF, ETN

Substantially Equivalent Devices:	*New Cadwell Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Cadwell Zenith System	K143440, K180181	Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) / Natus Quantum (primary)
		K162199	Cadwell Industries Inc. / Cascade IOMAX Interoperative Monitor (secondary)

510(k) Summary

Device Description: The Cadwell Zenith System is a high channel-count Electroencephalogram (EEG) system capable of cortical stimulation via the optional stimulator and built in switch matrix. The system is capable of acquiring, storing, and reviewing neurophysiological data and report generation.

The Cadwell Zenith System can be configured in a portable or fixed room configuration. Carts are available for purchase with the system.

The Cadwell Zenith System consists of one (1) or more Zenith amplifiers, an IOMAX Base Module, and an optional IOMAX Cortical Module. Additionally, a Patient Event Button, USB Photic Stimulator, and USB Footswitch can be purchased separately

Indications for Use: 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 and post-operative testing on patients of all ages.

Technology Comparison: The Cadwell Zenith System employs the same technological characteristics as the predicate device.

Characteristic	*Proposed Device*	*Predicate Device*
Population	Patients of all ages.	Patients of all ages, but is not designed for fetal use
System Configuration	Computer based equipment with dedicated hardware peripherals/components, and custom acquisition software.	Computer based equipment with dedicated hardware peripherals/components, and custom acquisition software.
Modalities	Electroencephalogram (EEG) External cortical stimulation Photic stimulation Video	Electroencephalogram (EEG) External cortical stimulation Photic stimulation - Pulse oximetry

510(k) Summary

Characteristic	*Proposed Device*	*Predicate Device*
Amplifier Channels	144 channels per amplifier, cascade-able up to 576 channels • 144 referential channels per amplifier • 8 differential channels per amplifier • 0 DC channels per amplifier	128 channels per amplifier, cascade-able up to 256 channels • 128 referential channels per amplifier • Up to 8 configurable differential channels per amplifier • 16 DC channels per amplifier
Number of Amplifiers that can Connect to Recorder	Four (4)	Two (2)
Input Impedance	1 GΩ	>1000 MΩ
Input Noise	<1.5 µV peak-to-peak at 01.-100 Hz	<2.0 µV peak-to-peak at 01.-100 Hz
Input Signal Range	> 25 mV peak-to-peak	20 mV peak-to-peak
Maximum DC Input Voltage Offset	> ±500 mV	±300 mV
Common Mode Rejection Ratio	>110 dB at 60Hz	>106 dB at 60 Hz
Sampling Frequency	1 MHz	256, 512, 1024, 2048, 4096, 8192, 16384 Hz
Storage Rate	Up to 8 kHz	
Sampling A/D Resolution	24 bits	24 bits
Cortical stimulator output	Output mode: Low Output type: Constant current	Output mode: Low Output type: Constant current

510(k) Summary

Summary of Performance Testing:

Software

The Cadwell acquisition software is 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, Am1: 2015, Medical device software - Software life cycle processes*

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

Electrical Safety

The Cadwell Zenith System was tested for performance in accordance with the following standard:

- *ANSI/AAMI ES60601-1: 2005/(R)2012, Am1: 2012, C1:2009/(R)2012, A2:2010/(R)2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Test results indicate that the Cadwell Zenith System complies with the applicable standards.

Electromagnetic Compatibility

The Cadwell Zenith System was tested for performance 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 Cadwell Zenith System complies with the applicable standards.

510(k) Summary

Performance Testing – Bench

The Cadwell Zenith System was tested for performance in accordance with internal requirements and the following standards:

- *IEC 60601-2-26: 2012, Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs*
- *IEC 60601-2-40: 2016, Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment*
- *IEC 60601-1-6: 2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
- *IEC 62366-1: 2015, Medical devices – Application of usability engineering to medical devices.*

Test results indicate that the Cadwell Zenith System complies with its predetermined specifications and the applicable standards.

Conclusion

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

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