July 17, 2018

Cadwell Industries, Inc.
Alison Hull
EEG Product Manager
909 North Kellogg Street
Kennewick, Washington 99336

Re: K180269
Trade/Device Name: Cadwell Apollo System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GWE, GWL, OLT, OLV, OMC
Dated: April 17, 2018
Received: April 18, 2018

Dear Alison Hull:

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.

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)*
K180269

Device Name
Cadwell Apollo System

Indications for Use *(Describe)*
The Cadwell Apollo System is indicated for prescription use to acquire, record, transmit, and display physiological and environmental data for electroencephalographic (EEG) and polysomnographic (PSG) ambulatory and/or clinical studies of 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K180269
510(k) Summary

Submitter's Name and Address	Cadwell Industries, Inc. 909 North Kellogg Street Kennewick, WA 99336
Contact Person	Ms. Alison Hull Phone: +1 (800) 245-3001, Extension 210 Email: alisonh@cadwell.com
Date Summary Prepared	July 6, 2018
Trade Name	Cadwell Apollo System
Common Name	Electroencephalograph (EEG)
Classification Name & Product Code	**PRIMARY** Class II 21 CFR 882.1400 GWQ Full-montage Standard Electroencephalograph **SUBSEQUENT** 21 CFR 882.1400 OLT Non-normalizing Quantitative Electroencephalograph Software 21 CFR 882.1400 OLV Standard Polysomnograph (PSG) with Electroencephalograph 21 CFR 882.1400 OMC Reduced-Montage Standard Electroencephalograph 21 CFR 882.1890 GWE Evoked Response Photic Stimulator 21 CFR 882.1835 GWL Physiological Signal Amplifier
Predicate Device	**K133355 Cadwell Flex EEG/PSG** 21 CFR 882.1400; GWQ Subsequent Product Codes GWE, GWL OLT, OLV, OMC

<table>
<tr><td>Device Description</td><td colspan="3">The Cadwell Apollo System (Apollo) is used to acquire, record, transmit, and display physiological and environmental data for ambulatory electroencephalograph (EEG) and polysomnography (PSG) and/ or clinical studies of patients of all ages.

The Apollo system consists of a Recorder, a 64-channel and/or 32-channel Amplifier, a patient event button, a microphone, and various connecting cables. Optional accessories include the Arc photic stimulator, a video recording camera, and a cart for the equipment. Previously FDA cleared accessories used with the Apollo system consist of various electrodes, leads, and cables.

The Apollo system utilizes Cadwell Arc acquisition software (previously cleared in K133355) with support for Apollo hardware using single or combinations of amplifiers, and a photic stimulator.

Additional channels can be added with multiple amplifiers.
Apollo is intended for use in both home healthcare and professional healthcare environments.</td></tr>
<tr><td>Indications for Use</td><td colspan="3">The Cadwell Apollo System is indicated for prescription use to acquire, record, transmit, and display physiological and environmental data for electroencephalographic (EEG) and polysomnographic (PSG) ambulatory and/or clinical studies of patients of all ages.</td></tr>
<tr><td rowspan="12">Comparison of Technological Characteristics to Predicate Device</td><td>Characteristic</td><td>K133355
Predicate Device</td><td>K180269
Subject Device</td></tr>
<tr><td>Intended Patient Population</td><td>All ages</td><td>Same</td></tr>
<tr><td>System Configuration</td><td>Computer based equipment with dedicated hardware peripherals/components</td><td>Same</td></tr>
<tr><td>Recording Modality</td><td>Attended and unattended</td><td>Same</td></tr>
<tr><td>Intended Environment of Use</td><td>Hospital or home</td><td>Same</td></tr>
<tr><td>Recorder to Personal Computer (PC) Connectivity/ Networking</td><td>Wired via an Ethernet cable</td><td>Wired via a USB cable</td></tr>
<tr><td>Recorder to Amplifier Connectivity</td><td>Wired via a cable</td><td>Same</td></tr>
<tr><td>Amplifiers Available</td><td>32 channel amplifier</td><td>32 channel amplifier
64 channel amplifier</td></tr>
<tr><td>Sampling Rage</td><td>3200 Hz</td><td>1 MHz</td></tr>
<tr><td>Other Inputs</td><td>8 active/ reference, 2 other</td><td>Up to 10 active/reference, 2 other</td></tr>
<tr><td>Impedance Check</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Number of Amplifiers that can Connect to Recorder</td><td>One (1)</td><td>Two (2)</td></tr>
</table>

	Continued: Comparison of Technological Characteristics		
	Characteristic	**K133355** **Predicate Device**	**K180269** **Subject Device**
	Power Source	Rechargeable Batteries (D Alkaline) or USB powered	Rechargeable Batteries (3.8V 3880 mAh Lithium Ion Battery) or USB powered
	Acquisition Software	Arc	Same
	Arc Sentinel Software, a Central Nurse Station	No	Yes; for viewing and monitoring multiple data records
	Remote Monitoring	Yes	Same
	Photic Flash Rate	1 to 60 Hz	Same
	Photic Interface	USB	Same
	Microphone Input Ability	Yes	Yes
	Wireless Communication Capability	No	Yes; wireless communication capability between Recorder and PC with Arc acquisition software.
	CMMR	> 92 dB	Improved; > 110 dB
	Recording Duration	> 48 hours per 2 D batteries	Up to 96 hours on battery; Unlimited on battery
	Storage Rate	250 Hz	16 kHz
	Other Inputs	Patient Event Button Patient Microphone Q-Video Mobile 2 (in-home recordings)	Patient Event Button Patient Microphone Q-Video Mobile 3 (in-home recordings)
	Cameras	IP and USB Cameras	IP and USB Cameras

Summary of Nonclinical Testing to Demonstrate Substantial Equivalence	
Software	The Arc acquisition software corresponds to a MODERATE level of concern. Software was designed and developed per a robust software development process, and was verified and validated. Software information is provided in accordance with internal requirements, the following guidance documents, and IEC software standard: ● FDA guidance: *The content of premarket submissions for software contained in medical devices,* issued May 11, 2005. ● FDA guidance: *Off-the-shelf software use in medical devices,* issued September 09, 1999. ● FDA guidance: *General principles of software validation; Final guidance for industry and FDA staff*, issued January 02, 2011. ● *FDA guidance: Content of premarket submissions for management of cybersecurity in medical devices,* October 02, 2014. ● *IEC 62304: 2006, Medical device software - Software life cycle processes* Test results indicate that the Arc acquisition software conforms to predetermined specifications and the applicable software guidance documents.
Electrical Safety	The Apollo System was tested for performance in accordance with the following standard: ● *IEC 60601-1: 2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.* ● *IEC 60601-1-11: 2010, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* ● *ISO 15004-2: 2007, Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection* Test results indicate that the Apollo System conforms to the above standards.
Electromagnetic Compatibility	The Apollo was tested for performance in accordance with the following standard: ● *IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.* Test results demonstrate that the Apollo conforms to the above standard.

Performance Testing – Bench	The Apollo 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 60601-1-6: 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.* Test results indicate that the Apollo conforms to its predetermined specifications and the above standards.
Conclusion	The results of the aforementioned performance data demonstrate that the Cadwell Apollo System is substantially equivalent to the Cadwell Flex EEG/PSG.