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

September 29, 2020

Re: K201819
Trade/Device Name: Cadwell Apollo System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: June 30, 2020
Received: July 1, 2020

Dear Brad Weeks:

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,

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

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)*
K201819

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."

Traditional 510(k) Summary K201819

Date Prepared:	September 29, 2020
Submitter:	Cadwell Industries, Inc. 909 North Kellogg Street Kennewick, WA 99336
Submitter and Application Correspondent	Mr. Brad Weeks Phone: +1 (800) 245-3001, Extension 232 Email: bradw@cadwell.com
Manufacturing Site:	Cadwell Industries, Inc. 909 North Kellogg Street Kennewick, WA 99336
Trade Name:	Cadwell Apollo System
Common and Classification Name:	Electroencephalograph
Primary Classification Regulation:	21 CFR §882.1400
Primary Product Code:	GWQ- Full-Montage Standard Electroencephalograph
Secondary Product Codes & Regulations:	GWE, GWL, OLT, OLV, OMC 21 CFR §882.1890; 21 CFR §882.1835

Predicate Device:

Cadwell Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Cadwell Apollo System	**K180269**	Cadwell Industries Inc. / Cadwell Apollo System

Traditional 510(k) Summary K201819

Device Description: The Cadwell Apollo System (Apollo) is used 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.

The Apollo system utilizes Cadwell Arc acquisition software (previously cleared in K180269) with support for Apollo hardware using single or combinations of amplifiers, a photic stimulator, and interfaces with a Cadwell or 3rd party oximeter devices. Additional channels can be added with multiple amplifiers.

Apollo is intended for use in both home healthcare and professional healthcare environments.

Indications for Use: 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.

Technology Comparison: The Apollo employs the same technological characteristics as the predicate device.

Characteristic	***Predicate Device K180269***	***Subject Device K201819 Cadwell Apollo System***
Population	Patients of all ages.	Same.
Indications for Use	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.	Same; No changes to the IFU
System Configuration	Computer based equipment with dedicated hardware peripherals/components	Same.
Recording Modalities	Attended or unattended	Same.
Use Environment	Hospital or home	Same.
Recorder to Personal Computer (PC) Connectivity/ Networking	Wired	Wired or Wireless

Recorder to Amplifier Connectivity	Wired	Same.
Amplifiers Available	32 channel amplifier 64 channel amplifier	Same
Oximeters Available	No.	3rd party or a Cadwell oximeter interface compatible
Number of Amplifiers that can Connect to Recorder	Two (2)	Same
Acquisition Software	Arc	Same.
Arc Sentinel	Yes.	Same
Remote Monitoring	Yes	Same.
Photic Flash Rate	1 to 60 Hz	Same.
Photic Interface	USB	Same.

Summary of Performance Testing:

Software

The Arc acquisition 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 Arc acquisition software complies with its predetermined specifications and the applicable guidance documents.

Electrical Safety

The Apollo 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 complies with the applicable 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 indicate that the Apollo complies with the applicable standards.

Wireless Co-existence Testing

The Apollo was tested for performance in accordance with the following standard:

- *ANSI C63.27:2017, American National Standard for Evaluation of Wireless Coexistence*
- *AIM 7351731:2017, Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers*
- *FCC 15C Intentional Radiators*
- *47 CFR1.1307(b), 1.1310 SAR Requirements*

Traditional 510(k) Summary K201819

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 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 Apollo. The results of these activities demonstrate that the Apollo is as safe, as effective, and performs as well as or better than the predicate devices.

Therefore, the Apollo is considered substantially equivalent to the predicate devices.