DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 8, 2016

Cadwell Industries, Inc.
John Cadwell Jr.
Electrical Engineer
909 N. Kellog St.
Kennewick, Washington 99336

Re: K161027
Trade/Device Name: Cadwell AmpliScan
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMA
Dated: August 12, 2016
Received: October 3, 2016

Dear Mr. Cadwell:

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 yours,

Michael J. Hoffmann -A

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)*
K161027

Device Name
Cadwell AmpliScan

Indications for Use *(Describe)*

1) Cadwell AmpliScan is a software-only device indicated for use with electroencephalographic (EEG) data from Cadwell Arc application software. Cadwell AmpliScan is distributed solely for use with Cadwell Arc software.

2) The Cadwell AmpliScan device is for prescription use only by qualified medical practitioners, trained in Electroencephalography, who will exercise professional judgement when using the information.

3) This device does not provide any diagnostic conclusion about the patient's condition to the user.

4) Cadwell AmpliScan uses electroencephalographic (EEG) data to calculate and display a quantitative aEEG measure. This quantitative measure should always be interpreted by the user in conjunction with review of the original EEG waveforms. The aEEG quantitative measure of Cadwell AmpliScan is intended to monitor the state of the brain.

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.

510k Summary

1) Submitter:

Cadwell Industries, Inc.
909 N. Kellogg Street
Kennewick, Washington 99336

Phone: 509-735-6481

Contact Person: John A Cadwell Jr.
Date Prepared: August 12, 2016

2) Device:

Trade Name of Device: Cadwell AmpliScan
Common or Usual Name: Cadwell AmpliScan aEEG software
Classification Name: Electroencephalograph (21 CFR 882.1400)
Regulatory Classification: Class II
Product Code: OMA

3) Predicate Device:

Persyst 12 EEG Review and Analysis Software (K132306) is a predicate.
This predicate has not been subject to a design-related recall.

Olympic CFM6000 (K031149) is a reference predicate.
This reference predicate has not been subject to a design-related recall.

4) Device Description:

Cadwell AmpliScan is a software-only device distributed solely for use with the application software commonly known and marketed as Cadwell Arc software. Cadwell Ampliscan software is installed with installation of Arc software, and does not require installation or removal separate from the Arc application.

The Cadwell AmpliScan software-only device applies the Amplitude-Integrated EEG (aEEG) algorithm referred to as the Cerebral Function Monitor (CFM) to stored data within the Cadwell Arc software, and stores and displays the results.

5) Indications for Use:

1) Cadwell AmpliScan is a software-only device indicated for use with electroencephalographic (EEG) data from Cadwell Arc application software. Cadwell AmpliScan is distributed solely for use with Cadwell Arc software.

2) The Cadwell AmpliScan device is for prescription use only by qualified medical practitioners, trained in Electroencephalography, who will exercise professional judgement when using the information.

3) This device does not provide any diagnostic conclusion about the patient's condition to the user.

4) Cadwell AmpliScan uses electroencephalographic (EEG) data to calculate and display a quantitative aEEG measure. This quantitative measure should always be interpreted by the user in conjunction with review of the original EEG waveforms. The aEEG quantitative measure of Cadwell AmpliScan is intended to monitor the state of the brain.

6) Comparison of Technological Characteristics with the Predicate Device:

A comparison is made between Cadwell AmpliScan and the aEEG functionality of the predicate.

Cadwell AmpliScan and the predicate device both utilize the Maynard and Prior "Cerebral Function Monitor (CFM)" implementation to perform amplitude-integrated EEG analysis on stored patient data and display the results. The CFM requires input filtering, signal compression, low pass filtering, and specific display characteristics. Given that the Cadwell AmpliScan and the predicate implement the required analysis on input data in the same way, the respective outputs of Cadwell AmpliScan and the predicate are equivalent.

The following table illustrates technological characteristics of Cadwell AmpliScan and the predicate.

	Persyst 12 EEG Review and Analysis Software (K132306)	Cadwell AmpliScan aEEG
Device Type	Software-only	SAME
aEEG	YES	SAME
Product Codes	OMA, ORT, OLT	OMA
aEEG Algorithm	Cerebral Function Monitor Maynard and Prior	SAME
Input Filter	Per CFM, Maynard and Prior	SAME
Signal Compression	Linear 0-10 uV, Log10 10-100uV	SAME
Low Pass Filter Time Constant	0.5 S	SAME
Vertical Display	Linear 0-10 uV, Log10 10-100uV	SAME
Horizontal Display	Vertical line display from min to max within each epoch	SAME
aEEG Indications for Use	"The aEEG functionality…is intended to monitor the state of the brain"	SAME
Supported Input Data	"As recorded by OEM EEG equipment being used to acquire the EEG signal" including: Cadwell, Natus, Compumedics, Nihon-Kohden, and others.	CADWELL ARC EEG Data

The following technological differences exist between the subject and predicate devices:

- The predicate device can utilize stored EEG data from a wide range of sources, including Cadwell, Natus, Compumedics, Nihon-Kohden and others. The Cadwell AmpliScan limits the supported input data to EEG data stored in the Cadwell Arc environment.
- The predicate device is a standalone software product that can be integrated into a variety of vendor's application software. The Cadwell AmpliScan software is integrated only into Cadwell Arc application software.

No new issues of safety or effectiveness are introduced by the differences.

7) Performance Data:

The following performance data was provided in support of the substantial equivalence determination:

Software Verification and Validation Testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for the device was considered moderate level of concern.

In the Substantial Equivalence Discussion, a comparison of outputs from Cadwell AmpliScan and the predicate with like input data demonstrate the resulting equivalence of analysis and display.

Given that the Cadwell AmpliScan is a software-only device, biocompatibility, electrical safety and electromagnetic compatibility, mechanical testing, bench testing, clinical testing, and animal testing were not applicable.

Summary:
Based on the device performance as documented in this submission, Cadwell AmpliScan was found to have a safety and effectiveness profile that is similar to the predicate device.

8) Conclusions:

The Cadwell AmpliScan is substantially equivalent to predicate device in design, intended use, technology, and function. The included data supports the safety and efficacy of the device, and software verification and validation demonstrate Cadwell AmpliScan performance is comparable to the predicate for the intended use.