K133355

JAN 29 2014

CADWELL 510k Summary

Submitter:	Cadwell 909 N. Kellogg Street Kennewick, Washington 99336 509-735-6481
Contact Person:	John Cadwell Jr Electrical Engineer Cadwell Laboratories, Inc.
Date Prepared:	October 31, 2013
Trade Name:	Cadwell Flex
Regulation Name:	Electroencephalograph, Evoked Response Photic Stimulator, Physiological Signal Amplifier
Regulation Number:	21 CFR 882.1400, 21 CFR 882.1890, 21 CFR 882.1835
Regulatory Classification:	Class II
Product Code:	GWQ, OMC, OLV, GWL, OLT, GWE, GWL
Classification Panel:	Neurological
Predicate Devices:	EB Neuro BE micro Trea (K093728) Cadwell Kilowin (K971214)
Device Description:	The Cadwell Flex EEG/PSG system consists of: (1) acquisition hardware that can acquire, record, store, and transfer up to 32 channels of EEG data, 8 active-reference signal, and audio signals from a microphone, and has EzNet-module-compatibility, (2) software that allows a user to acquire, store, transmit, view and print data, and to create reports based on the data, (3) optional video recording, (4) an optional photic stimulator, and (5) a host electronic device (typically a PC) capable of running the software and interfacing with the acquisition, video recording, and photic stimulation devices. The Cadwell Flex EEG/PSG system is capable of two modes of operation: (1) Ambulatory, where the acquisition hardware acquires, records, and stores physiological and/or

environmental data to onboard mass-storage non-volatile memory, and said data is later transferred to a host electronic device, and (2) Clinical, where the host electronic device is connected to the acquisition hardware during data acquisition and recording, with mass-storage occurring on the host.

The Cadwell Flex EEG/PSG system software is capable of interfacing with additional software used to perform EEG/PSG waveform analysis.

Indications for Use:

Indications for Use: The Cadwell Flex 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.

Substantial Equivalence:

Using the characteristics shown in the following table, the Cadwell Flex is shown to be substantially equivalent to the referenced predicate devices.

Product	EBNeuro BEmicro	Kilowin	Cadwell Flex
510K	K093728	K971214	TBD
Device class	Class II	Class II	Class II
Product Codes	OLV, GWQ, GWL, MNR, DQA	GWE, GWF, GWJ, GWQ, IKN, JXE, OLT, OLV	GWQ, OLV, GWL, OLT, GWE
Target Population	Pediatric through adult	Patients of all ages	Patients of all ages
Recording Modality	Attended and unattended	Attended	Attended or unattended
Use Environment	Hospital and home	Operating room or clinic	Hospital or home
Prescription Status	Available only on the order of a physician	By prescription only	By prescription only
Power	Battery powered or USB powered	AC power	Battery powered or USB powered
Number of EEG Channels	21	24-64	32
Other Inputs	1 digital	12 ECG and 1-16 EMG	8 active/reference, 2 other
A/D Resolution	16 bit	16 bit	16 bit
Sampling Rate	Up to 2048 samples/s	3200 Hz	3200 Hz
Impedance Check	Yes	Yes	Yes

Testing:	Software and hardware verification and validation, and electromagnetic compatibility and safety testing were performed.
Conclusion:	The Cadwell Flex system is substantially equivalent to predicate devices in design, use, technology, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 29, 2014

Cadwell Laboratories
c/o Mr. John Cadwell Jr.
909 N. Kellogg Street
Kennewick, WA 99336

Re: K133355
Trade/Device Name: Cadwell Flex
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalogram
Regulatory Class: Class II
Product Code: GWQ, OMC, OLV, GWL, OLT, GWE
Dated: October 13, 2013
Received: October 13, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
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 on last page.

510(k) Number *(if known)*
K133355

Device Name
Cadwell Flex

Indications for Use *(Describe)*
The Cadwell Flex 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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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