CADWELL 510k Summary

K140552

JUL 2 3 2014

Submitter:	Cadwell Laboratories, Inc.
Contact Person:	Chris Bolkan Safety / Regulatory Specialist Cadwell Laboratories, Inc. 909 N. Kellogg Street Kennewick, WA 99336 Phone: (509) 735-6481 Fax: (509) 783-6503
Date Prepared:	February 27, 2014
Trade Name:	Cadwell Spike and Seizure Detector
Common Name:	Spike and Seizure Detector
Classification Name and Number:	Electroencephalograph, Class II, 21 CFR 882.1400
Product Code:	OMB
Classification Panel:	Neurology
Predicate Device:	Persyst Reveal (K011397)
Device Description:	Cadwell Spike and Seizure Detector is a software-only product with an algorithm intended to analyze and mark events that correspond to spikes and seizures for the purpose of reviewing EEG recording. This application is for use by trained users such as neurologists, clinicians, registered EEG technicians. It requires EEG data recorded with a standard montage using the 10/20 electrode placement. The detected events are annotated on the EEG record for review by a trained user.
Indications for Use:	*Cadwell Spike and Seizure Detector* is a software-only product with an algorithm intended to analyze and mark events that may correspond to epileptiform discharge (spike) and electrographic seizure for the purpose of reviewing scalp EEG recordings. The marked events are reviewed, deleted, and interpreted by qualified clinical

practitioners who will exercise professional judgment in using the information.

This device does not control the delivery of energy, administration of drugs, or another form of life sustaining function to the patient. It is intended for use in patients who are 18 years or over.

This device does not provide any diagnostic conclusion about the patient to the user.

Summary of technology characteristics:

Key Attributes	Comparison	
	Cadwell Spike and Seizure Detector (K123927)	**Persyst Reveal (K011397)**
Identifies spikes	Yes	Yes
Identifies seizures	Yes	Yes
Displays calculated EEG measures	No	No
User-adjustable seizure detection	No	Yes
Users can add/delete events	Yes	Yes
Type of EEG recording supported	Scalp EEG only	Unknown
Type of EEG analysis	Post-hoc only	Post-hoc only
Population age	Adult	Unknown
Product Code	OMB	GWS

Table 1: Device Comparison Table

Substantial Equivalence: The Cadwell Spike and Seizure Detector is a software package that identifies spike and seizures in scalp EEG recordings. Persyst Reveal is commercially available software package that identifies spike and seizures in scalp EEG recordings and is an accepted standard in automated spike and seizure detection programs.

The Cadwell Spike and Seizure Detector is substantially equivalent to the Persyst Revel in terms of:

- Indications for use
- Technology characteristics
- Performance characteristics

- Testing results from clinical data

Validation:

76 records were selected from unique patients with the following inclusion criteria:

- Patient age 18 years or over on the date of recording
- Full montage scalp EEG using the 10-20 montage was acquired
- Total recording duration of minimum 6 hours

All recordings were acquired in an epilepsy monitoring unit as part of routine clinical protocol using the standard 10-20 montage. The patient age range for the selected recordings was 18-92 years with an average age of 48.2 years. The recording duration was in the range of 6-71 hours with an average of 24.6 hours.

Three human experts reviewed the complete raw EEG for each record and marked spike and seizure events. Majority rule (agreement between any two of three experts) using any overlap method was applied to construct the reference set.

The reference set for spike detector validation contained a total of 946 events. Figures 1 and 2 show the performance for each of the experts, Persyst Reveal and Cadwell Spike Detector.

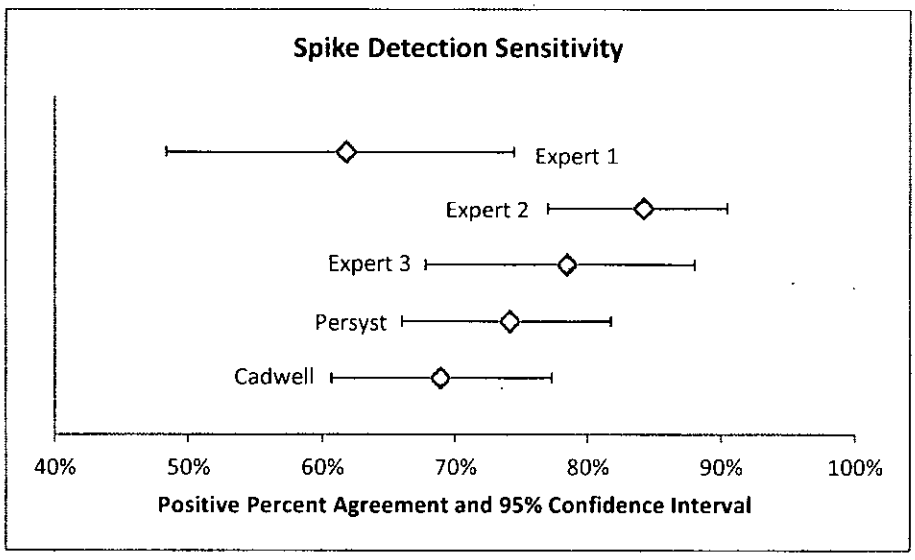

Figure 1: Positive percent agreement and 95% confidence interval using bootstrap method.

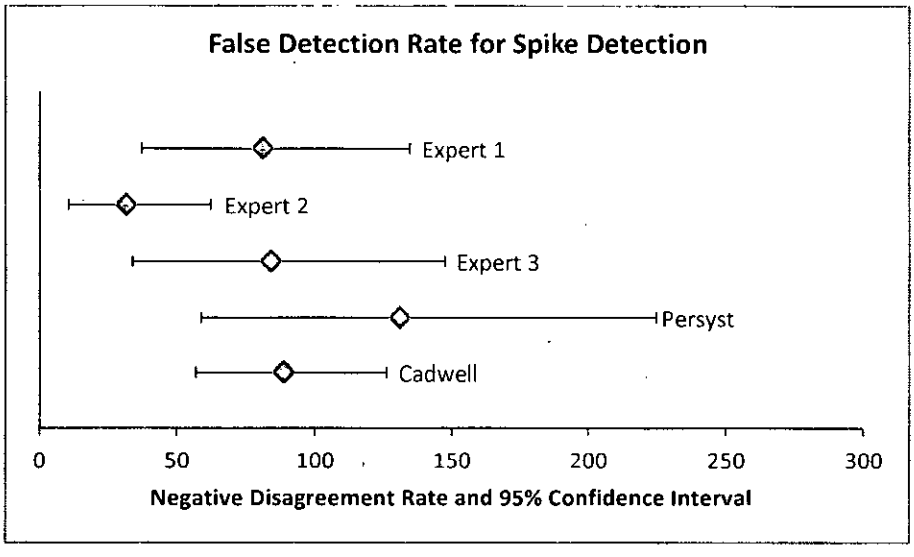

Figure 2: Negative disagreement rate and 95% confidence interval using bootstrap method.

The reference set for seizure detector validation contained a total of 332 events. Figures 3 and 4 show the performance for each of the experts, Persyst Reveal and Cadwell Seizure Detector.

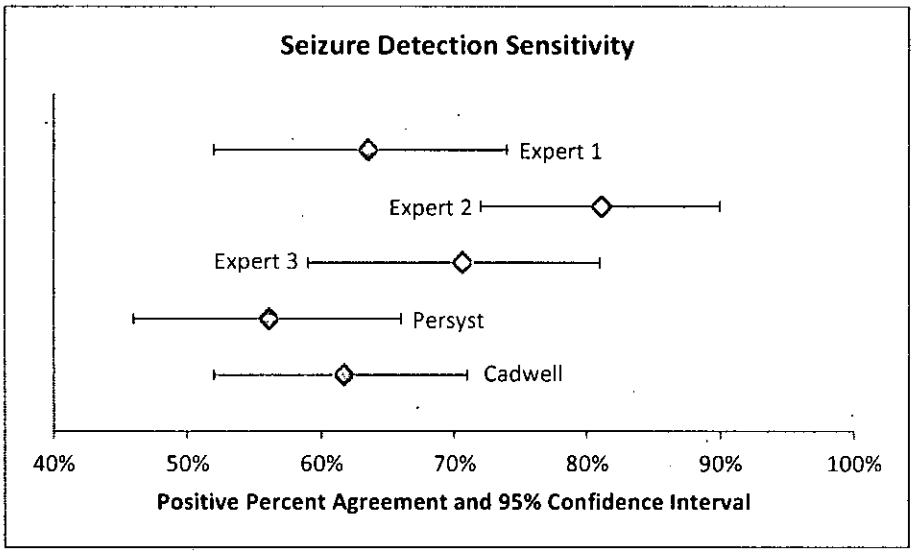

Figure 3: Positive percent agreement and 95% confidence interval using bootstrap method.

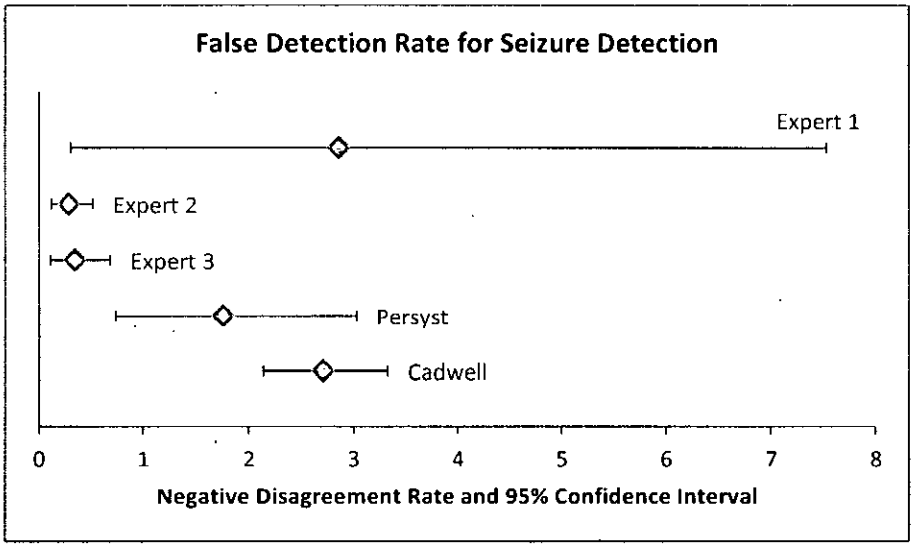

Figure 4: Negative disagreement rate and 95% confidence interval using bootstrap method.

Conclusion: The validation results show that the Cadwell Spike and Seizure Detector meets the objective for device effectiveness and substantial equivalence.

Test Criteria	Spike Detector	Seizure Detector
Device effectiveness	Pass	Pass
Substantial equivalence	Pass	Pass

Table 2: Summary of the test results for the Cadwell Spike and Seizure Detector

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

July 23, 2014

Cadwell Laboratories
Jinesh Jain, Software Manager
909 N. Kellogg Street
Kennewick, WA 99336

Re: K140552
Trade/Device Name: Cadwell Spike and Seizure Detector Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB
Dated: June 9, 2014
Received: June 17, 2014

Dear Mr. Jain:

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" (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 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,

Felipe Aguel -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140552

Device Name
Cadwell Spike and Seizure Detector

Indications for Use *(Describe)*
Cadwell Spike and Seizure Detector is a software-only product with an algorithm intended to analyze and mark events that may correspond to epileptiform discharge (spike) and electrographic seizure for the purpose of reviewing scalp EEG recordings. The marked events are reviewed, deleted, and interpreted by qualified clinical practitioners who will exercise professional judgment in using the information.

This device does not control the delivery of energy, administration of drugs, or another form of life sustaining function to the patient. It is intended for use in patients who are 18 years or over.

This device does not provide any diagnostic conclusion about the patient to the user.

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)*

Felipe Aguel -S Date: 2014.07.23 19:45:51 -04'00'

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."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."