



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

Cadwell Laboratories, Inc
c/o Mr. Carlton Cadwell
President and CEO
909 North Kellogg Street
Kennewick, Washington 99336

APR - 9 2012

Re: K971214
Trade/Device Name: Kilowin
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLT, GWQ, IKN, JXE, OLV, GWF, GWE, GWJ
Dated (Date on orig SE ltr): February 19, 1998
Received (Date on orig SE ltr): March 13, 1998

Dear Mr. Cadwell:

This letter corrects our substantially equivalent letter of June 11, 1998.

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,


Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510K Supplement 1- Indications for Use

Date: April 16, 1997

510(K) Number: K971214

Device Name: Kilowin

Indications for Use:

Kilowin is an electroneurodiagnostic device designed to measure and display the electrical signals generated by peripheral nerve, muscle and central nervous system. It will acquire the data necessary for electroencephalography (EEG), electronystagmography (ENG), electrocardiography (ECG), electromyography (EMG), nerve conduction velocity (NCV, F wave, and H reflex), evoked potentials (EP, brainstem, visual, somatosensory), repetitive nerve stimulation and sleep assessment.

The Kilowin instrument is designed for use during the duration of the procedure only.

Use of the proposed device is to be administered under the direction of a trained physician, surgeon, neurologist, or electrophysiologist in an operating room or clinic.

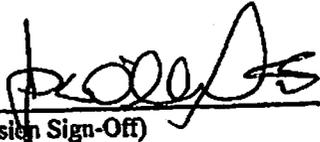
The Kilowin device(s) are intended for use during electroencephalography (EEG), electronystagmography (ENG), electromyography (EMG), nerve conduction velocity (NCV, F wave, and H reflex), evoked potentials (brainstem, visual, somatosensory), repetitive nerve stimulation testing and sleep assessment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use v
(Per 21 CFR 801.109)

OR

Over the Counter Use



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971214