



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Building 66  
Silver Spring, MD 20993-0002

AUG 14 2009

The Electrode Store, Inc.  
c/o Carl Youngmann, Ph.D., RAC  
Designated Regulatory and Quality Affairs Representative  
1530 Holcomb St.  
Port Townsend, WA 98368

Re: K083758

Trade/Device Name: Sensory Nerve Electrodes-Two Finger Rings, Stimulator Probe  
Electrodes-Facial  
Regulation Number: 21 CFR 882.1320  
Regulation Name: Cutaneous Electrode  
Regulatory Class: II  
Product Code: GXY  
Dated: June 30, 2009  
Received: July 2, 2009

Dear Dr. Youngmann:

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.

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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

**Section IV—Indications for Use Statement**

510(k) Number: K083758

Device Name: The Electrode Store™ Sterile Cutaneous Electrode

Indications for Use:

The Electrode Store™ Sterile Cutaneous Electrode is indicated for use as a recording (active/reference) or stimulating electrode during electromyography (EMG), including nerve conduction studies (NCS) and evoked potential (EP) recordings. It is provided packaged and labeled as a sterile device for single patient use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Henry D. Campbell

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K083758

Prescription Use X  
(Per 21 CFR §801 subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR §801 subpart C)