



DEPARTMENT OF HEALTH & HUMAN SERVICES

M2716n

June 21, 1999

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-25

Mr. Timothy S. Cooke
President
The Electrode Store, Inc.
159 W. Mason Avenue
P.O. Box 1112
Buckley, Washington 98321

WARNING LETTER

Dear Mr. Cooke:

On April 12-14, 1999, Engineer Dennis G. Kawabata collected information that revealed a serious regulatory problem involving the electrodes manufactured by your firm. The specific products are:

1. **Re-usable monopolar and concentric needle electrodes** (models RTM-12, 25, 37, 50, 75; DMR-25, 37, 50; RC-25, 37, 50; JO-5TH & JO-5TR; GK-50, 75; SDN-313, 323);
2. **Surface (cutaneous) electrodes** EMG use: re-usable bar electrodes, re-usable disc electrodes [single and paired], sensory nerve electrodes, re-usable ground electrodes, stimulator probes; EEG use: disposable needle electrodes for use, single disc electrodes for use, detachable disc electrodes for use, ribbon strand electrodes for use, and ear clip electrodes for use;
3. **Needle electrodes for EEG use** (models DEN-12, DEN-12SAF, PRO-E12, PRO-E12SAF).

The Federal Food, Drug, and Cosmetic Act (Act), a United States Federal law, considers these electrodes to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires manufacturers of medical devices to obtain marketing clearance for their products from the Food and Drug Administration before they may offer them for sale.

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This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your products for sale. In reaching our decision we have carefully considered your correspondence dated April 29, 1999, in which you responded to the inspectional observations. Based upon your correspondence and our review, we have the following comments:

With regard to the reusable monopolar and concentric needle electrodes (paragraph 1, above), CDRH has determined that a 510(k) is necessary because the indications have been changed from single use to multiple use. We note that you have chosen to discontinue marketing the monopolar and concentric needle electrodes. Should you in the future choose to market these reusable electrodes, you will need to submit premarket notification.

Concerning the surface (cutaneous) electrodes and needle electrodes for EEG use (paragraphs 2 and 3, above), 510(k)s are required for the following reasons. The use of surface electrodes for EEG is considered a new use. Additionally, the indication for use is affected when the electrode application is changed from surface to needle. The needle electrodes, which were cleared under K926094, were for EMG use only, not EEG use.

Some of the above-described electrodes may be pre-amendment. The kind of information you need to submit in order to obtain clearance for those devices you consider to be pre-amendment is described in the enclosed materials. The FDA will evaluate this information and decide whether your products may be legally marketed.

Marketing your products is a violation of the law until you have clearance from FDA. The products are adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your products are adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your devices are safe and effective. Your products are misbranded under the Act because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed.

This is a serious violation of the law and may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your

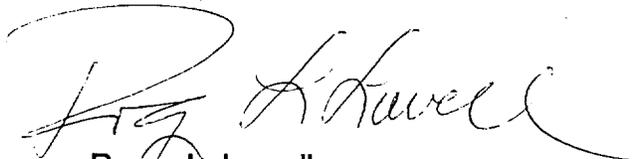
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product inventory, obtaining a court injunction against further marketing of the products, or assessing civil money penalties. Other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Thomas S. Piekarski, Compliance Officer, at the above mailing address.

There are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

Sincerely,

A handwritten signature in black ink, appearing to read "Roger L. Lowell", written in a cursive style.

Roger L. Lowell
District Director

Enclosures:
Premarket Notification
Documentation Required for Preamendment Status