



FEB 05 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Tu
Everyway Medical Instruments Co., Ltd.
3 Fl., No. 5, Lane 155, Peishen Rd., Sec. 3
Shen Keng Hsiang, Taipei Hsien 222, Taiwan, R.O.C.

Re: K012463

Trade/Device Name: Lifecare: 5 x 5 CM Square, 4 x 4 CM Square, 5 CM Round, 7.5 CM Round, 4 x 6 CM Oval, 5 x 10 CM Oval, 4 x 8 CM Rectangle, 5 x 10 CM Rectangle

Regulation Number: 21 CFR 882.1320

Regulation Name: Cutaneous electrode

Regulatory Class: Class II

Product Code: GXY

Dated: November 8, 2001

Received: November 13, 2001

Dear Mr. Tu:

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.

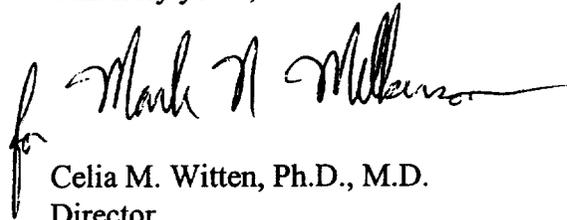
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012463

Device Name: Lifecare Neurostimulation Electrode

Indications For Use:

The Lifecare electrodes are intended to be used with transcutaneous neurostimulation devices. Some common types of neurostimulation devices include, but are not limited to, TENS devices and powered muscle stimulation devices. Transcutaneous neurostimulation electrodes are passive devices serving as an interface between a patient's skin and a neurostimulation device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Miller

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K012463