K050788

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5. 510(K) STATEMENT

MAY 13 2005

" 510(k) SUMMARY "

Submitter's Name: ***EVERLIFE Medical Instrument Co., Ltd.***
No. 58, Fu-Chiun Street, Hsin Chu City, 30067, Taiwan, ROC

Date summary prepared: March 18, 2005

Device Name:

Proprietary Name: EVERLIFE, Various Models of Self Adhesive Electrodes, AP series

Common or Usual Name: Self Adhesive Electrodes

Classification Name: GXY, Class II
21 CFR 882.1320

Indications for Use:

Intended to be applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

Biocompatibility Testing:

- Cytotoxicity study – ISO 10993-5
- Skin irritation study – ISO 10993-10
- Skin sensitization study – ISO 10993-10

Legally marketed device for substantial equivalence comparison:

HOME CARE Various Models of Self-Adhesive Electrodes, K022917

Summary for substantial equivalence comparison:

The intended uses for the two devices are almost the same, because the new device can also be used for EEG, ECG, EMG, TENS, and Muscle stimulation cases. Though the gel ingredients or the conductive films for the two devices may be different, the effect of impedance levels for the intended situations is assured for both of the devices, and the safety and effectiveness hazards are not present, and they are considered to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2005

Everlife Medical Instrument Co., Ltd.
C/o: Dr. Jen, Ke-Min
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City
China (Taiwan) 300

Re: K050788
Trade/Device Name: EVERLIFE, Various Models of Self Adhesive Electrodes, AP series
Regulation Numbers: 21 CFR 882.1320
Regulation Names: Cutaneous Electrode
Regulatory Class: II
Product Code: GXY
Dated: March 18, 2005
Received: March 28, 2005

Dear Dr. Jen, Ke-Min:

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), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K 050788

Device Name: *EVERLIFE, Various Models of Self Adhesive Electrodes, AP series*

Indications for Use:

Intended to be applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)

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

Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K050788