K082065

510(K) SUMMARY

APR 10 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:

Company Name:	Well Life Healthcare Limited
Contact person:	Jenny Hsieh
Address:	1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C.
TEL No.:	886-2-2928-2112
Fax No.:	886-2-2928-1880
E-mail address:	jenny@welllifehealthcare.com.tw

Date of Summary Preparation: July 14, 2008.

2. Device Identification:
Classification Name: Electrode, Cutaneous
Trade/Proprietary Name: Well Life Self Adhesive Electrode / CM, FA, PU, and SP series
Predicate devices: K062675 (Gemore Technology Co., Ltd)

3. Device Description
Well Life Self Adhesive Electrode / CM, FA, PU, and SP series are non-sterile, disposable laminated, flexible structures composed of the following three main construction layers:

First Layer – the exterior layer which may be made of the following different type of material coated with adhesive : white fabric(CM), white foam(FA), printed plastic film(PU) or silicon pad(SP).

Second Layer – Conductive plastic film.

Third Layer – Biocompatible conductive hydrogel coupling media

The electrodes are designed for single-patient/multiple application use. Because of the adhesive nature of the biocompatible hydrogel, no securing materials are required to secure the device to the patient's skin. The electrode has one type of connection point that can be used to connect the stimulation device to the electrodes. This connection point is compatible with all standard, marketed Neurostimulation and muscle-stimulation devices.

For the electrical connection, Well Life provides two different types:
1> Snap Series – Snap connection – 1.65" standard size of mail. Snap is provided to connect to the wire female snap.
2> Wire Series – Lead wire assembly – 4.5" ~ 6" wire with .080 in. diameter female socket connected to one side of the wire.

4. Predicate Technological Characteristics Comparison:

Well Life Self Adhesive Electrode / CM, FA, PU, and SP series are technologically equivalent to the predicate devices. They are physically and technically similar to the those currently being marketed for "Neurostimulation" i.e., TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) and PGS (Pulsed Galvanic Stimulation).

Since currently the above mentioned devices (TENS & EMS) are capable of being sold as both prescription and OTC medical device, we claimed that our electrodes are capable of being sold at both prescription and OTC TENS and EMS device application so as to fit that marketing requirement.

5. Safety and Effectiveness:

Well Life Self Adhesive Electrode / CM, FA, PU, and SP series are as safe and effective as the K062675 (Gemore Technology Co., Ltd) which was previously found to be substantially equivalent to the 510(K) cleared models via 510(k) Premarket Notifications.

The first safety issue consideration is whether or not the skin contact gel, which is used to adhere the electrode to the skin to transfer the electric current to the use patient, would cause any skin irritation. To ensure the conformity of this biocompatibility issue, we use the Axelgaard gel which has been proved suitable for the use in the skin contact part for the Axelgaard 510(K) cleared electrode with 510(K) number K983741 and K000947, or the other alternative biocompatibility material with ISO-10993 conformity certificate. All of them have passed the required skin sensitivity testing criteria as specified in the Tripartite Biocompatibility Guidance for Medical Devices and ISO 10993-1 requirements for skin contact.

For the electricity performance, we have conducted and completed the electrical safety testing according to the chosen performance standard, ANSI/AAMI EC12. The testing report was included in this submission.

6. Conclusion:

Based upon the above mentioned information. Well Life considers its Self Adhesive electrodes to be as safe and effective as the predicate devices being marketed and manufactured by: K062675 (Gemore Technology Co., Ltd).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Well-Life Healthcare Ltd.
% Ms. Jenny Hsieh
1 FL, No. 16, Lane 454 Jungjeng Rd.
Yunghe City, Taipei County
Taiwan, R.O.C

APR 10 2009

Re: K082065
Trade/Device Name: Well-Life Self Adhesive Electrodes/CM, FA, PU, and SP models
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 7, 2009
Received: March 9, 2009

Dear Ms. Hsieh:

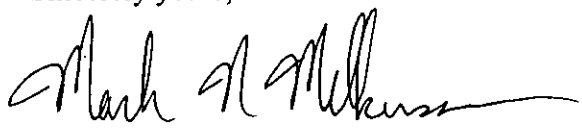
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,



Mark N. Melkerson
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):

Device Name: Well Life Self Adhesive Electrode / CM, FA, PU and SP series

Indications For Use:

The Well Life Self Adhesive Electrode / CM, FA, PU and SP series are intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Well Life Self Adhesive Electrode / AP, CM, FA, PU and SP series are designed and intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) and PGS (Pulsed Galvanic Stimulation).

Prescription Use √ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K082065