JUN 2 5 2010

510(K) Summary

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

The assigned 510(k) number is: K100399

1. Submitter's Identifications:

Company Name:	Well Life Healthcare Limited
Contact person:	Jenny Hsieh
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2. Name of the Device:

4 Channels Multiple Modes Electrical Stimulator/ Model: NuvoStim IV, WL-2504A

3. Information of the 510(k) Cleared Device (Predicate Device):

WL-2203A (K033857), WL-2204A(K033857),WL-2204A -P2(K033857), and WL-2206D(K092763)

4. Device Description:

The Well-Life 4 Channels Multiple Modes Electrical Stimulator/ Model: WL-2504A is the combination of transcutaneous electrical nerve stimulator(TENS) and Interferential stimulation (IF) used for pain relief and/or powered muscle stimulator(EMS) by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the situation of patient.

The Well-Life 4 Channels Multiple Modes Electrical Stimulator/ Model: WL-2504A consist mainly of two parts: the stimulus generator, electrode. The stimulus generator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the patient's skin so as to transmit this stimulus current to the patient for pain relief or muscle stimulation of intended use purpose.

The Well-Life 4 Channels Multiple Modes Electrical Stimulator/ Model: WL-2504A includes several different operation modes as mentioned on the comparison table. These operation modes are generated from the software control by using the microprocessor as its main control unit.

5. Intended Use:

The indication for use as described hereafter :

Transcutaneous Electrical Nerve Stimulator (TENS/IF TENS) & Program can be used for the following applications :

- For symptomatic relief of chronic intractable pain.

Neuromuscular electrical stimulation (NMS) & Program stimulation can be used for the following applications :

- Relax muscle spasms
- Prevent or retard disuse atrophy
- Increase local blood circulation
- Re-educate muscles
- Maintain or increase the range of motion

6. Substantial Equivalence Comparison

The WL-2504A has output characteristics and controls that are identical to those of the predicate devices. The new device WL-2504A is considered as Substantial Equivalent to the function of chosen 510K chosen predicate devices:
1> The TENS function of WL-2504A is substantial equivalent to WL-2203A (K033857).
2> The NMS function of WL-2504A is substantial equivalent to WL-2204A (K033857).
3> The Program function of WL-2504A is substantial equivalent to WL-2204A-P2 (K033857).
4> The IF TENS function of WL-2504A is substantial equivalent to WL-2206D (K092763).

7. Output Performance Range for each Operation Mode

- Current Density Range: Unit mA/cm^2..(measured against 500Ω loading at maximum pulse rate).

Function	Operation Function			
	IF TENS	TENS	EMS	Pre-program
Minimum	< 0.001	< 0.001	< 0.001	< 0.001
Moderate	0.0281	0.09	0.1125	0.09
Maximum	0.1125	0.18	0.225	0.18

- Power Density Range: Unit W/cm^2 (measured against 500Ω loading at maximum pulse rate).

Function	Operation Function			
	IF TENS	TENS	EMS	Pre-program
Minimum	< 0.001	< 0.001	< 0.001	< 0.001
Moderate	0.0281	0.0018	0.00281	0.0018
Maximum	0.1125	0.0072	0.01125	0.0072

8. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, and EN 60601-1-2 requirement.

In addition to the compliance of voluntary standards, the risk assessment has been carried out according to ISO-14971:2007, and the software verification has been carried out according to the FDA software validation guidance.

9. Conclusions

The 4 Channels Multiple Modes Electrical Stimulator , model WL-2504A , has the same intended use and technological characteristics as the cleared device of WL-2203A (K033857), WL-2204A (K033857),WL-2204A -P2(K033857), and WL-2206D (K092763). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 25 2010

Well-Life Healthcare Limited
c/o Ms. Jenny Hsieh
Official Correspondent
1FL, No.16, Lane 454, Jungjeng Road
Yunghe City, Taipei County
China (Taiwan)

Re: K100399
Trade/Device Name: 4 Channels Multiple Modes Electrical Stimulator / Model: NuvoStim IV, WL-2504A
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Codes: GZJ, IPF, LIH
Dated: May 27, 2010
Received: May 28, 2010

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

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

Indications For Use

510(k) Number (if known): k100399

Device Name: 4 Channels Multiple Modes Electrical Stimulator /
Model: NuvoStim IV, WL-2504A

Indications For Use:

The indication for use of this device includes the prescription TENS, NMS, Interferential stimulation as follows:

Transcutaneous Electrical Nerve Stimulator (TENS/IF TENS) & Program can be used for the following applications :

- For symptomatic relief of chronic intractable pain.

Neuromuscular electrical stimulation (NMS) & Program stimulation can be used for the following applications :

- Relax muscle spasms
- Prevent or retard disuse atrophy
- Increase local blood circulation
- Re-educate muscles
- Maintain or increase the range of motion

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)

k100399

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number