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: K090023

JAN 30 2009

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.
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E-mail address:	jenny@welllifehealthcare.com.tw

2. Name of the Device:

IF series True sine interferential stimulator / Model: WL-2206B & WL-2106E.

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

WL-2206A2 (K060975).

4. Device Description:

The WL-2206B and WL-2106E are the device which generates the small true-sine pulses of electrical current. The generated current may be delivered to the patient skin and/or underlying nerves through the cable and electrode placed on skin.

5. Intended Use:

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

In addition, the standard format for the statement of indications and contraindication for use are provided hereafter.

6. Substantial Equivalence Comparison

The WL-2206B and WL-2106E have output characteristics and controls that are identical to those of the predicate device. The new devices are different in that WL-2106E is controlled using knobs and multi-position switches versus input buttons in conjunction with an LCD display. WL-2206B is functionally identical to WL-2206A2.

7. 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 software verification has been carried out according to the FDA software guidance.

8. Conclusions

The true sine interferential stimulator, model WL-2206B & WL-2106E, has the same intended use and technological characteristics as the cleared device of WL-2206A2 (K060975). 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
9200 Corporate Boulevard
Rockville MD 20850

Well Life Healthcare Limited
% Ms. Jenny Hsieh
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Jungjeng Road
Yunghe City, Taipei County
Taiwan, R.O.C

JAN 30 2009

Re: K090023
Trade/Device Name: IF series True sine interferential stimulator/Model: WL-2206B & WL-2106E
Regulatory Class: Unclassified
Product Code: LIH
Dated: January 5, 2009
Received: January 5, 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.

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or 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

510(k) Number (if known):_____

Device Name: IF series True sine interferential stimulator / Model: WL-2206B & WL-2106E.

Indications For Use:

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V OR Over-The-Counter Use ___

(Optional Format 1-2-96)