Well-Life Healthcare Ltd.

K072168

510(K) SUMMARY

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:
   Well-Life Healthcare Ltd.
   1 Fl., No. 16, Lane 454, Jungjeng Rd., Yunghe City,
   Taipei County, Taiwan, R.O.C.

   Contact:
   Ms. Jenny Hsieh
   General Manager

   DEC 1 9 2007

   Date of Summary Preparation: November 23, 2007.

2. Name of the Device:

Trade name:	Well-Life OTC Abdomen System; model WL-2412.
Common name:	Powered Muscle Stimulator
Classification name:	Stimulator, Muscle, Powered
Product Code:	NGX

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

   For this 510(k) submission, we compared our models to the following FDA cleared OTC devices:
   - K010335: Slendertone Flex, made by Bio-Medical Research Ltd.

4. Device Description:

   The Well-Life OTC ABDOMEN SYSTEM model WL-2412 is battery-operated programmable muscle stimulator intended to improve or facilitate muscle performance by applying an electrical current to electrodes, which are attached on abdomen.

   Well-Life OTC ABDOMEN SYSTEM model WL-2412, consists mainly of three parts: the stimulator , electrodes, and support belts fitting for special parts of body. The stimulator 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 specified region, so as to transmit this stimulus current to the region of abdomen for the following intended purposes:

   - Strengthening, toning and firming of the abdomen region.

   To adequately locate the stimulation on the intended treatment area, the following support belt is provided together with the stimulator:

   - The abdomen belt, which is capable of connecting to the both two output channels of stimulator.

The stimulation mode for Well- Life OTC ABDOMEN SYSTEM 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:

Basically the indication for use is defined clearly as the description of the following table:

Model Name	Statement of "indication for use"	Intended for
WL-2412	The electrical muscle stimulator intended for the following indication for use: • Strengthening, toning and firming of the abdomen region.	OTC

6. 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, EN 60601-1-1, 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.

7. Conclusions

The Well Life OTC ABDOMEN SYSTEM, model WL-2412, has the same intended use and technological characteristics as the cleared device of Slendertone Flex (K010335). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted model 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. Therefore, the Well Life OTC ABDOMEN SYSTEM, model WL-2412, is substantial equivalent to the chosen predicate model.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2007

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

Re: K072168
Trade/Device Name: Well-Life OTC Abdomen System, Model WL-2412
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: November 23, 2007
Received: November 26, 2007

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 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

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: OTC Abdomen System / Model: WL-2412.

Indications For Use:

The WELL-LIFE OTC Abdomen System / Model WL-2412 is the electrical muscle stimulator intended for the following indication for use:

- Strengthening, toning and firming of the abdomen region.

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 K072168