Well Brain International LTD.
威盛國際有限公司

JUL 11 2012

510(k) Summary of Safety and Effectiveness
This summary is submitted in accordance with 21 CFR 807.92

1. **Submitter's name:**
Well Brain International, Ltd
Room 1212 Harbour Crystal Centre
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Hong Kong SAR, China

Establishment registration number:
3004950644

Name of contact person and title:
Victor K Wai
Managing Director

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Date of preparation:
March 28 2011

2. **Proprietary name / Model number of the device:**
Gymform Dual Flex Belt/ WB-162

Common name:
Powered Muscle Stimulator/Therapeutic Vibrator

Classification name:
Stimulator, Muscle, Power, For Muscle Conditioning; and Vibrator, Therapeutic

Classification Product code:
NGX and IRO

3. **Predicate Device:**
Predicate device selected for comparison of the electric muscles stimulation (EMS) mode is the Slendertone FLEX Abdominal Training System Type 515 powered muscle stimulator; assigned with the 510(k) number of K030708 to Bio-Medical Research Ltd of Ireland cleared to market commercially in the United States.

4. **Description of device:**

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The new device with its proprietary name/model number of Gymform Dual Flex Belt/WB-162 is a single device featured with two modes of operation, independent each other - the electrical muscle stimulation for abdominal muscles conditioning and the therapeutic vibrator for abdominal muscles relaxation.

Upon selected the electrical muscle stimulator (EMS) mode, the flex belt will function as an electrical muscle stimulator capable to achieve toning and firming of muscles in the abdominal region via using transcutaneous electrical muscle stimulation which is a technology for muscle conditioning by sending a stream of electric impulses to the motor nerve of muscle via the pair of single-patient/multiple-application biocompatible cutaneous electrodes on the inner surface of the flex belt, the muscle responds to each electric impulse by producing a contractile twitch, just as it would create voluntary muscle contractions during normal training & strengthening practice, and continues to contract until the electric impulse is over the muscle then returns to its relax state. The level of muscle contraction and relaxation is determined by the electric impulse intensity and the duration applied to the motor nerve of muscle, in which is user selectable via the flex belt control panel.

Upon selected the therapeutic vibrator (Vibration) mode, the Gymform Dual Flex Belt (new device) will function as a therapeutic vibrator to perform muscles relaxation. The therapeutic vibrator (Vibration) mode employs the method of electric muscle massage that simulates natural massage movement of a massage therapist, using oscillating movement of the eccentric motor that installed in the instrument casing to produce linear pulling vibrations to relaxing the abdominal muscle region of a patient. Although therapeutic vibrators are classified as a Class I device, the ***Gymform Dual flex belt/WB-162*** is considered a Class II device because it combines a powered muscle stimulator (classified under 21 CFR 890.5850 as Class II) with a therapeutic vibrator (classified under 21 CFR 890.5975 as Class I).

The Gymform Dual Flex Belt (new device) is manufactured by the submitter, the Well Brain International Ltd, with her production facility in China where a Quality Management System of ISO 9001:2008 and ISO13485:2003 is certified and currently maintained for the manufacturing of medical devices.

5. **Intended Use:**
The Gymform Dual Flex Belt is a single device featured with two modes of operation, independent each other - the electrical muscle stimulation (EMS) for abdominal muscles conditioning and the therapeutic vibrator (Vibration) for abdominal muscles relaxing.

Indications for Use:
The electrical muscle stimulation (EMS) mode of the Gymform Dual Flex Belt is indicated for the improvement of abdominal muscle tone, and for the development of a firmer abdomen.

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The therapeutic vibrator (Vibration) mode of the Gymform Dual Flex Belt is indicated for the promotion of muscle relaxation.

6. **Key Technological characteristics comparison**
The electric muscles stimulation (EMS) mode of the Gymform Dual Flex Belt and the Slendertone FLEX Abdominal Training System Type 515 (K030708) are designed, developed and built on the technology of transcutaneous electrical muscle stimulation (EMS), otherwise known as neuromuscular electrical stimulation (NMES). Both devices use electric impulses that generated by an electric pulse generator to conduct thru skin contact electrodes onto the abdominal muscle region of the patient to achieve muscles conditioning. The electric muscles stimulation (EMS) mode of the Gymform Dual Flex Belt and the Slendertone FLEX Abdominal Training System Type 515 (K030708)use the totally-enclosed concept that electrodes are wrapped by the flex belt connected to the studs of its electric pulse signal generator built inside the flex belt, become an integral part; such design eliminates the use of external lead wires/patient cables for conductivity needs, helps to prevent undesired interference to the electrodes when operating. For the most part, chances of misuse are substantially reduced as electrodes are pre-positioned in the flex belt restricted to use only on the patient's abdominal region.

7. **Key Technological characteristics comparison:**
Chart below compares the spec sheet between the Gymform Dual Flex Belt and the Slendertone FLEX Abdominal Training System Type 515 (K030708):

Primary parameters	**Gymform Dual Flex Belt WB-162 (500Ω load each channel)**	**Slendertone FLEX Abdominal Training System Type 515 (500Ω load each channel)**
Number of channels	Single	Dual
Waveform	Symmetrical Biphasic	Symmetrical Biphasic
Output frequency (Hz)	14/18/25/28/33	45 - 75
Positive pulse width (μs)	230	200 - 300
Negative pulse width (μs)	230	200 - 300
Number of programs	5	7
Program duration (min)	20, 21, 22 & 24	20,25 & 30
Max intensity levels each program	30	99
Power source	12V AC Adapter	3x 1.5V AAA Batteries

The Gymform Dual Flex Belt output is different from Slendertone FLEX Abdominal Training System Type 515, but both devices comply with FDA safety requirements and comply with

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safety standard IEC 60601-2-10. Moreover, the effectiveness test report of Gymform Dual Flex Belt demonstrates that the new device has same effectiveness of predicate device.

8. **Non-clinical Studies:**
Testing of the Gymform Dual Flex Belt for the conformity of recognized consensus standards that outlined below has been successfully performed to assure of safety and efficacy.

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004).
- IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.
- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.

9. **Substantial equivalence:**

The electric muscles stimulation (EMS) mode of the Gymform Dual Flex Belt and the Slendertone FLEX Abdominal Training System Type 515 (K030708) are designed, developed and built on the identical technology of electrical muscle stimulation whereby technological characteristics and applications are acquired. Although to some degree there are differences in product specifications, verification and validation tests demonstrated the Gymform Dual Flex Belt maintains same safety and effectiveness as that of the cleared predicate device, the Slendertone FLEX Abdominal Training System Type 515 (K030708). More importantly, the electric muscles stimulation (EMS) mode of the Gymform Dual Flex Belt (new device) is indicated for use on abdominal muscles conditioning which is essentially identical to the predicate device, the Slendertone FLEX Abdominal Training System Type 515 (K030708) that legally marketed in the United States.

Conclusion:
There are unlikely any significant differences existing between the electric muscles stimulation (EMS) mode of the Gymform Dual Flex Belt (new device) and the Slendertone FLEX Abdominal Training System Type 515 (K030708), and should not raise any new issues of safety and effectiveness.

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

Well Brain International, Limited
% Mr. Victor K. Wai
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Hong Kong SAR, China

JUL 11 2012

Re: K111781
Trade/Device Name: Gymform Dual Flex Belt
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX, IRO
Dated: July 09, 2012
Received: July 09, 2012

Dear Mr. Wai:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Well Brain International LTD.
維盛國際有限公司

(04) Indications for Use Statement

510(k) Number (To be assigned)

Device Name: Gymform Dual Flex Belt

Indication for Use:

The electrical muscle stimulation (EMS) operation mode is indicated for the improvement of abdominal muscle tone, and for the development of a firmer abdomen.

The therapeutic vibrator (Vibration) operation mode is indicated for the promotion of muscle relaxation.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 801 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 Surgical, Orthopedic,
And Restorative Devices

510(k) Number K111781