Chapter 6. 510(k) Summary

K130074

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- 510(k) Owner's Name: Well Brain International Ltd.
- Establishment Registration Number: 3004950644
- Address: Room 1212, Harbour Crystal Centre, No. 100 Granville Road, Tsim Sha Tsui East, Kowloon, Hong Kong SAR, China
- Phone: (852) 2619-0833
- Fax: (852) 2429-0960
- Contact Person: Victor K Wai
- Email: victor@wellbrain-intl.com

AUG 1 5 2013

2. Subject Device Information

- Trade Name: GYMFORM® ABS-A-ROUND, Model: VDPGYCIND0016
- Common Name: Powered muscle stimulator
- Classification name: Stimulator, Muscle, Powered, For muscle conditioning
- Review Panel: Physical Medicine
- Product Code: NGX
- Regulation Class: 2
- Regulation Number: 890.5850

3. Predicate Device Information

Sponsor	Leto Enterprises Incorporation	Well Brain International Ltd.	Contour Technology	Prospera Corporation	SPORT-ELEC S.A.
Device Name	X2ABS Dual Channel Fitness Belt	Gymform Dual Shape flex belt	Contour Technology Muscle Stimulator, Model: MX9	Prospera OTC TENS Electronic Pulse Massager	Body Control System "4M"

510(k) Number	K102295	K111781	K111476	K122744	K092476
Product Code	NGX	NGX	NGX	NGX	NGX
Regulation Number	890.5850	890.5850	890.5850	890.5850	890.5850
Regulation Class	2	2	2	2	2

4. Device Description

The ABS-A-ROUND is a three-channel battery operated muscle stimulation system specifically designed to training muscles.

The 3-area belt is intended for use on the muscles in abdomen, left waist and right waist alternately. The stimulation of each channel is active alternately for 2 cycles with its set output intensity level and mode program in below default activation sequence: F channel is active for 180 seconds solely, stop for 10 seconds as idle interval; then L channel is active for 180 seconds solely, stop for 10 seconds as idle interval; then R channel is active for 180 seconds solely, stop for 10 seconds as idle interval; repeat one cycle with above activation sequence.

The Mini belt accessory is intended for use on the muscles in arms, legs (lower extremities), thighs and buttocks areas separately.

It is comprised of an electronic stimulator module for signal generation, two belts for fixation, and electrodes for signal connection to skin. The electrodes are replaceable.

Power is derived from 3 batteries located in a compartment protected by a removable battery cover for the Fitness Belt. There is no current passed from side to side.

The stimulator sends gentle electrical current to targeted muscle group through the electrodes placed on the skin. The parameters of the unit are controlled by the buttons. Its intensity level can be adjustable by user.

5. Intended Use / Indications for Use

The GYMFORM® ABS-A-ROUND is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The ABS-A-ROUND may be considered a technique or method for muscle training.

The 3-area belt is intended for use on the muscles in abdomen, left waist and right waist alternately.

The Mini belt accessory is intended for use on the muscles in arms, legs (lower extremities), thighs and buttocks areas separately.

6. Performance Summary

Testing has been carried out to assure compliance with recognized electrical safety standards:

- IEC 60601-1 and IEC 60601-2-10 standards for electrical safety

- IEC 60601-1-2 standard for electromagnetic compatibility

Performance data has been verified according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices".

The waveform test report has also been provided to verify the parameters of the device.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of GYMFORM® ABS-A-ROUND is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device					Remark
Device Name and Model	GYMFORM® ABS-A-ROUND	X2ABS Dual Channel Fitness Belt	Gymform Dual Shape flex belt	Contour Technology Muscle Stimulator, Model: MX9	Prospera OTC TENS Electronic Pulse Massager	Body Control System '4M'	--
510 (K) Number	Applying	K102295	K111781	K111476	K122744	K092476	--
Intended Use & Indications for Use	The GYMFORM® ABS-A-ROUND is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The ABS-A-ROUND may be considered a technique or method for muscle training. The 3-area belt is intended for use on the muscles in abdomen, left waist and right waist alternately. The Mini belt	The X2ABS Dual Channel Fitness Belt is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes: - Improvement of muscle tone of the muscles in the abdomen.	The Gymform Dual Shaper flex belt is a powered muscle stimulator intended for abdominal muscle conditioning.	The Contour Technology Muscle Stimulator is intended to stimulate healthy muscles in order to improve or facilitate muscle performance . The Contour Technology Muscle Stimulator may therefore be considered a technique or method for muscle training. The Contour Technology Muscle Stimulator Ab Belt accessory is	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.	The Body Control -4M' is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes. Improvement of muscle tone and firmness, for strengthenin g muscles in arms, abdomen,	SE Note 1

	accessory is intended for use on the muscles in arms, legs (lower extremities), thighs and buttocks areas separately.			intended for use on abdominal muscles only for strengthening and toning of abdominal muscles. The Contour Technology Muscle Stimulator BackPad accessory is intended for use on the lower back muscles only.		thighs and buttocks areas.	
Specification							
Channel	3	2	1	2	2	2	SE Note 2
Synchronous /Alternating channels	Alternating	Synchronous	(1 Channel)	--	Alternating	--	SE
Stimulated muscles	Abdomen, left waist and right waist, arms, legs, thighs and buttocks	Abdomen	Abdomen	Abdomen and lower back	Shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg)	Arms, abdomen, thighs and buttocks areas	SE
Number of programs	6	8	5	--	3	4	SE Note 2
Number of phases variations	99 steps	28 steps	99 steps	--	--	--	SE Note 2
Number of adjustable independent outputs	3	2	1	--	3	2	SE
Output	From 0 to 118 V (From 0 to 1000 Ohm)	From 0 to 60 mA (From 0 to 1000 Ohm)	From 5.6 to 40 mA (From 0 to 500 Ohm)	From 0 to 22 mA (From 0 to 500 Ohm)	--	From 0 to 70mA from 0 to 60V- from 0 to 1000 Ohm)	SE Note 3
Frequency range(Hz)	2, 10, 50, 90, 120	8.5 to 64	15,18, 25,30, 35	1 to 120	1 to 100	50 to 70	SE Note 3
Pulse width range(μs)	100 / 120	220	250	340	120 to 6800	200	SE Note 3
Contraction and Relaxation time	Adjustable, due to different modes.	Adjustable, due to different modes.	Adjustable, due to different modes.	--	Adjustable, due to different modes.	Adjustable, due to different modes.	SE

Power	3 x 1.5V AAA batteries	2 x 1.5V AAA batteries	12V AC Adapter	4 x 1.5V AAA batteries	6V battery	3 x 1.5V AAA batteries	SE Note 4
Electrode Size (cm^2)	Small: 33.0 x 1 piece Big: 34.5 x 2 pieces	32	--	40.5	--	128	SE Note 5
Maximum Current Density(mA/ cm^2 @ 500Ω)	0.057 (for the smallest size electrode 33.0 cm^2)	0.032 (for the smallest size electrode 32.0 cm^2)	--	0.55 (for the smallest size electrode 40.5 cm^2)	1.4	--	SE Note 5
Timer Range	Default time (maximum) is 19 minutes.	Default time is 10 minutes, minimum time is 5 minutes	Default time is 10 minutes	--	15 minutes	Default time is 4 minutes 30 sec	SE
LCD display	Indicate the following information: Power on/off, Channel indication, Intensity level, Mode selection.	Indicate the following information: Sound on/off, Keylock, Low battery, Channel indication, Intensity level, Mode selection.	Indicate the following information: Sound on/off, Keylock, Low battery, Channel indication, Intensity level.	--	Indicate On/Off status only.	--	SE
Environment for operating	Temperature : 5 ~ 40°C Humidity: 20 ~ 65% RH	Temperature : 5 ~ 40°C Humidity: 20 ~ 65% RH	Temperature : 35°F to 95°F Humidity: 20 to 80% RH	--	--	--	SE Note 4
Environment for storage	Temperature : 0 ~ 40°C Humidity: 10 ~ 90% RH	Temperature : 0 ~ 40°C Humidity: 10 ~ 90% RH	Temperature : 32°F to 131°F Humidity: 10 to 90% RH	--	--	--	SE Note 4
Standards							
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	--	--	SE
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	--	--	SE

EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	--	--	SE

Comparison in Detail(s):

Note 1:

Although the muscles for intended use of subject device are different from predicate devices, we can find that the predicate device Contour Technology Muscle Stimulator (K111476), Prospera OTC TENS Electronic Pulse Massager (K122744) and Body Control System '4M' (K092476) can also be used on the same muscles according to the device description of 510(k) summary. So the subject device and predicate device K111476 have the same intended use aspect.

Note 2:

Although the number of channels, programs, and phase variations of subject device are different from the predicate devices, they are all compliance with IEC 60601-1 and IEC 60601-2-10 requirements. So the differences of the function specifications will not raise any safety or effectiveness issue.

Note 3:

Although the "Output", "Frequency range" and "Pulse width range" of subject device are a little different from the predicate devices, they are all compliance with IEC 60601-2-10 requirement and FDA guidance requirement for the EMS. So the differences of function specification will not raise any safety or effectiveness issue.

Note 4:

Although the power, operating and storage environment are a little different from the predicate devices, they are all compliance with IEC 60601-1 requirements. So the differences will not raise any safety or effectiveness issue.

Note 5:

Although the electrode size and maximum current density of subject device are a little different from the predicate devices, they are all compliance with IEC 60601-2-10 requirement and FDA guidance requirement for the EMS. So the differences of function specification will not raise any safety or effectiveness issue.

8. Date of the summary prepared: August 12, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 15, 2013

Well Brain International Ltd.
c/o Victor K Wai
Managing Director
Rm. 1212, 12 Floor, Harbour Crystal Centre
No. 100 Granville Road, Tsim Sha Tsui East
Kowloon, Hong Kong
China 999077

Re: K130074
Trade/Device Name: Gymform® ABS-A-ROUND, model VDPGYCIND0016
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: July 8, 2013
Received: July 11, 2013

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 contact 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. 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130074

Device Name: GYMFORM® ABS-A-ROUND, Model: VDPGYCIND0016

Indications For Use:

The GYMFORM® ABS-A-ROUND is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The ABS-A-ROUND may be considered a technique or method for muscle training. The 3-area belt is intended for use on the muscles in abdomen, left waist and right waist alternately. The Mini belt accessory is intended for use on the muscles in arms, legs (lower extremities), thighs and buttocks areas separately.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (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)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K130074