January 15, 2021

Well Brain International Ltd.
Jet Li
Regulation Manager
Guangzhou Kinda Biological Technology Co., Ltd
6F, No.1 TianTai road, Science City, LuoGang District,
GuangZhou, Guangdong
China

Re: K202653
Trade/Device Name: Gymform Total ABS
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 14, 2020
Received: December 18, 2020

Dear Jet Li:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather Dean, Ph.D.
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Rehabilitation Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202653

Device Name
Gymform® TOTAL ABS, Model: WB-245

Indications for Use *(Describe)*
The Gymform® TOTAL ABS (Model: WB-245) is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.
The large belt is intended for use on the muscles in abdomen. The small belt for working the leg and arm muscles, intended for use on the muscles in arms, legs (lower extremities) and thighs areas separately.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K202653

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) Sponsor: Well Brain International Ltd.
- Address: Room 1403 Fook Yip Building, 53-57 Kwai Fung Crescent, Kwai Chung, Hong Kong, China
- Phone: (852) 2619-0833
- Fax: (852) 2429-0960
- Contact Person: Victor K Wai
- Email: victor@wellbrain-intl.com

2. Subject Device Information

- Trade Name: Gymform® TOTAL ABS, Model: WB-245
- 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. Application Correspondent

Application Correspondent: Guangzhou KINDA Biology Technology Co.,Ltd.

- Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhouCity,China
- Contact Person: Mr. Jet Li
- Tile: Regulation Manager
- Tel: +86-18588874857
- Email:med-jl@foxmail.com

4. Predicate and Reference Device Information

510k Number	K130074 (Primary predicate)	K102295 (Reference device I)	K092476 (Reference device II)	K183674 (Reference device III)
Sponsor	Well Brain International Ltd	Leto Enterprises Incorporation	SPORT-ELEC S.A.	Shenzhen Leading Perfection Technology Co., Ltd
Device Name	ABS –A-Round	X2ABS Dual Channel Fitness Belt	Body Control System '4M'	Electronic Pulse Stimulator, Model S3
Product Code	NGX	NGX	NGX	NGX
Regulation Number	890.5850	890.5850	890.5850	890.5850
Regulation Class	2	2	2	2

5. Device Description

The Gymform® TOTAL ABS(Model: WB-245) consists of a control unit, large belt, small belt and electrode pads. The control unit enclosed in ABS plastic case. The device is design based on Microcurrent technology (Electro Muscle Stimulation-EMS) which uses a gentle current to condition, tone and strengthen muscles.

The Gymform® TOTAL ABS(Model: WB-245) is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The TOTAL ABS may be considered a technique or method for muscle training. It is a battery operated muscle stimulation system specifically designed to training muscles.

The large belt is intended for use on the muscles in abdomen. The small belt for working the leg and arm muscles, intended for use on the muscles in arms, legs (lower extremities) and thighs areas separately.

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.

There are 6 modes for output stimulation, and for each mode, there are 10 levels of output intensity can be choose. Default time is 10minutes for output stimulation.

Power is derived from 3 pieces of AAA batteries located in a compartment protected by a removable battery cover for the Fitness Belt.

6. Intended Use / Indications for Use

The Gymform® TOTAL ABS (Model: WB-245) is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

The large belt is intended for use on the muscles in abdomen. The small belt for working the leg and arm muscles, intended for use on the muscles in arms, legs (lower extremities) and thighs areas separately.

7. Performance data Summary

The Device has been evaluated the safety and performance by lab bench testing according to the following standards:

Electrical safety and electromagnetic compatibility (EMC)

1. IEC 60601-1-2: 2014: Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic Compatibility

2. IEC 60601-1:2005: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

3. IEC 60601-1-11: 2015: Medical Electrical Equipment - Part 1-11: General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

4. IEC 60601-2-10: 2012: Medical Electrical Equipment - Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

Biocompatibility testing

The biocompatibility evaluation for the device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of

Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Biological evaluation of medical device Part 10: Tests for Intracutaneos Reactivity test and skin sensitization (ISO 10993-10:2010)

- Biological evaluation of medical device Part 5: Cytotoxicity test- In vitro method (ISO 10993-5:2009)

Test	Test summary	Conclusion
Cytotoxicity test	Cytotoxicity Test with MTT Method according to ISO 10993-5	Non cytotoxic
Skin sensitization	Skin Sensitization with test method: 0.9% Sodium Chloride Injection Extract and Sesame Oil Extract according to ISO 10993-10	No skin sensitization
Intracutaneos Reactivity test	Skin Intracutaneos Reactivity with test method: 0.9% Sodium Chloride Injection Extract and Sesame Oil Extract according to ISO 10993-10	No skin irritation

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device.

Performance verification testing:

The waveform test report has also been provided to verify the parameters of the device. The below output current pulse waveform parameter was verified:

Output voltage, output current, Output waveform frequency, pulse width, maximum current and power density and so on were tested to demonstrate substantial equivalence to predicate devices.

Usability study testing:

Usability testing (OTC Study) was completed in 24 subjects to evaluate device human factors and label comprehension.

These usability study tests demonstrate that the device and its labeling can meet with the requirement:

1) the lay user can self-select themselves as being appropriate users of this device by the external box labeling, 2) the lay user can apply the treatment safely and correctly according to the instructions for use, and 3) the lay user can understand all indications, contraindications, warnings and precautions, and be able to identify whether they are within any contraindicated group; and be able to understand the user manual.

8. Clinical test

No clinical testing is need

9. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Gymform® TOTAL ABS(Model: WB-245) is substantially equivalent to the predicate devices quoted above.

Microcurrent technology (Electro Muscle Stimulation-EMS) is the technological principle for both the subject and predicate devices. . The device is design based on Microcurrent (Electro Muscle Stimulation-EMS) which uses a gentle current to condition, tone and strengthen muscles.

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

Elements of Comparison	Subject Device	Primary predicate	Reference device I	Reference device II	Reference device III	Remark
Sponsor	Well Brain International Ltd	Well Brain International Ltd	Leto Enterprises Incorporation	SPORT-ELEC S.A.	Shenzhen Leading Perfection Technology Co., Ltd	--
Device Name and Model	Gymform® TOTAL ABS, (Model: WB- 245)	ABS –A- Round	X2ABS Dual Channel Fitness Belt	Body Control System '4M'	Electronic Pulse Stimulator, Model S3	--
510 (K) Number	Applying	K130074	K102295	K092476	K183674	--
Indications for Use	The Gymform® TOTAL ABS(Model: WB-245)	The GYMFORM6 ABS-A-ROUND is intended to	The X2ABS Dual Channel Fitness Belt is intended for	The Body Control -4M' is intended for use by healthy	Mode 1 (PMS): To be used for stimulating healthy	Minor differenc e

	is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.. The large belt is intended for use on the muscles in abdomen. The small belt for working the leg and arm muscles, intended for use on the muscles in arms, legs (low er extremities) and thighs areas separately.	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 w aist and right w aist alternately. The Mini belt accessory is intended for use on the muscles in arms, legs (low er extremities), thighs and buttocks areas separately..	use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the follow ing purposes: - Improvement of muscle tone of the muscles in the abdomen.	persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the follow ing purposes. Improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas.	muscles in order to improve and facilitate muscle performance. Mode 2 (TENS): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities	Note 1 For predicat e device IV, only compare d w ith its indicatio n for use in EMS mode.
Channel	1	3	2	2	1	SE
Synchronous /Alternating channels	Synchronous	--	Synchronous	--	Symmetrical rectangular	SE
Stimulated muscles	Abdomen, arms, legs and thighs	Arms, Waist, abdomen, legs, thighs and buttocks areas	Abdomen	Arms, abdomen, thighs and buttocks areas	Arm, leg, abdomen, hip, feet	SE

Number of programs	6	6	8	4	1	SE

Number of output intensity level	10 steps	99 steps	28 steps	--	--	Minor difference Note 2
Maximum output voltage	81.6V @ 500Ω 96V @ 2kΩ 99.2V @ 10kΩ	108V @ 500 Ω 124V @ 2k Ω 126V @ 10k Ω	from 0 to 60V- from 0 to 1000 Ohm)	from 0 to 60V- from 0 to 1000 Ohm)	40±20% V @ 500 Ω 64±20%V @ 2k Ω 76±20% V @ 10k Ω	Minor difference Note 3
Maximum Output Current	163mA @ 500Ω 48mA @ 2kΩ 9.92mA @ 10kΩ	216mA@ 500 Ω 62mA@ 2k Ω 12.6mA@ 10k Ω	From 0 to 60 mA (From 0 to 1000 Ohm)	From 0 to 70mA	80±20% mA@500ohm; 32±20% @2kohm; 7.6±20% mA @10kohm	Minor difference Note 3
Frequency range(Hz)	50,60,70 Hz	2 Hz, 10 Hz, 50 Hz, 90 Hz, 120 Hz	8.5 to 64 Hz	50 to 70 Hz	Mode 1: 4-35Hz	Minor difference Note 3
Pulse w idth range(μs)	200	100 us / 120 us	220	200	200	Minor difference 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.	--	SE
Pow er	3 x 1.5V AAA batteries	3 x 1.5V AAA batteries	2 x 1.5V AAA batteries	3 x 1.5V AAA batteries	USB rechargeable battery, 3.7V	SE
Electrode Size (cm^2)	34.5 x 2 pieces; total 5 pairs of electrode pad	128	32	128	--	Minor difference Note 4

Maximum Current Density(mA/cm² @ 500Ω)	0.041 (mA/cm² @ 500Ω)	0.057 mA/cm² @ 500 Ω	0.032 (for the smallest size electrode 32.0 cm²)	--	Hips pad: 0.079 mA/cm² Arms and legs pad: 0.104 mA/cm² Abdomen pad: 0.111	Minor difference Note 5
					mA/cm² Feet pad: 0.016 mA/cm²	
Maximum pow er Density	28.81μW/cm²	53.8 uW/cm² @ 500 Ω	16. 38 μW/cm²	--	Hips pad: 100μW/cm²; Arms and legs pad: 200μW/cm²; Abdomen pad: 200μW/cm²; Feet pad:30μW/cm²	Minor difference Note 5
Timer Range	Default time is 10minutes.	Default time is 19 minutes	Default time is 10 minutes, minimum time is 5 minutes	Default time is 4 minutes 30 sec	25 min	Minor difference Note 6
LED display	Indicate the follow ing information: On/off status ,Mode selection.	--	Indicate the follow ing information: Sound on/off, Keylock, Low battery, Channel indication, Intensity level, Mode selection.	--	On/off status, Low battery	SE
Environment for operating	Temperature: 0 ~ 35° C Humidity: <85% RH	--	Temperature: 5 ~ 40° C Humidity: 20 ~ 65% RH	--	--	Minor difference Note 7
Environment for storage	Temperature: 0 ~ 40° C Humidity: 10 ~ 90% RH	--	Temperature: 0 ~ 40° C Humidity: 10 ~ 90% RH	--	--	SE
	All user directly contacting		All user directly		All user directly	

Biocompatibility	materials are compliance with ISO10993-5 and ISO10993-10 requirements.	--	contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	--	contacting materials are compliance w ith ISO10993-5 and ISO10993-10 requirements.	SE
Electrical Safety	Comply w ith IEC 60601-1 and IEC 60601-2-10	Comply w ith IEC 60601-1 and IEC 60601-2-10	Comply w ith IEC 60601-1 and IEC 60601-2-10	Comply w ith IEC 60601-1 and IEC 60601-2-10	Comply w ith IEC 60601-1 and IEC 60601-2-10	SE
EMC	Comply w ith IEC 60601-1-2	Comply w ith IEC 60601-1-2	Comply w ith IEC 60601-1-2	Comply w ith IEC 60601-1-2	Comply w ith IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

Even there is minor difference on the description words about Indications for use between subject device and predicate device. But actually, the indications for use and treatment parts are same to the primary predicate device I; And the indications for use of other predicate devices also cover the indications for use of subject device. So the differences of the statement of indications for use will not raise any safety or effectiveness issue.

Note 2:

There is difference on Number of output intensity level between subject device and predicate devices, but the key parameter which affect treatment should be output voltage, current, waveform. It's level number do not affect its treatment, So the differences of the level number of output intensity will not raise any safety or effectiveness issue.

Note 3:

For maximum output voltage, Maximum output current:

Even the maximum output voltage and current for the subject device are lower than the primary predicate device (K130074). The maximum output voltage and current reflect to the setting value of the highest intensity level of the device. Not each user need the highest intensity level, the user will change the level setting according to their muscle stimulation feeling when operation. And the subject device's max output voltage and output current value are covered in the output voltage and current range between primary predicate device and predicate device IV(K183674), so we can conclude that the minor difference of maximum output voltage/ output current between subject device and predicate devices would not affect effectiveness for the subject devices.

Although the “Frequency range” ,“Pulse width range” and of subject device are a little different from the primary predicate device I, but the other predicate devices output specification had been cover the specification range of subject device, and they are all compliance with IEC 60601-2-10 requirement and FDA guidance requirement for the EMS. So the minor differences of function specification will not raise any safety or effectiveness issue.

Note 4:

Although the electrode size of subject device are a little different from the predicate devices, the maximum current density and maximum power density are all compliance with IEC 60601-2-10 requirement and FDA guidance requirement for the EMS, and the electrode also had 510K clearance. So the differences of electrode size will not raise any safety or effectiveness issue.

Note 5:

Although maximum current density and maximum power 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.

And for the maximum power density difference:

For the power density difference, according to the Guidance Document for Powered Muscle Stimulator 510(k)s (page 14), the power density is related to the risk of thermal burning. And the maximum power density meet with the maximum allowed value 0.25 (W/cm²) required in FDA guidance.

The effectiveness of micro current mainly depend on the output current and output voltage; but not depend on the power density; And the power density (28.81μW/cm²) of subject device is in the range of predicate device (K130074) and the secondary predicate device (K102295), and for predicate device IV(K183674), its power density of 30 uW/cm² also was cleared in its 510K submission, which value is similar to the data of subject device.

Based on aforementioned discussion, we can conclude that the power density between the subject device and the predicate do not raise concerns of effectiveness for the subject device.

So the differences of maximum current density and maximum power density will not raise any safety or effectiveness issue.

Note6:

There is minor difference on treatment time range between subject device and predicate devices. But the treatment time can be adjusted by user as they want. So the differences of treatment time range will not raise any safety or effectiveness issue.

Note7:

Even there is some minor difference for operation environment between subject device and predicate device, but the operation environment do not affect the stimulation performance on body, and the device comply with IEC60601-1-11 and IEC60601-1; So the differences of treatment time range will not raise any safety or effectiveness issue.

Finial Conclusion:

The GYMFORM® TOTAL ABS，Model: WB-245 is substantially equivalence to the predicate devices.

10. Date of the summary prepared: January 14, 2021