October 10, 2019

Shenzhen OSTO Technology Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, 510663 CN

Re: K182136
Trade/Device Name: Intelligent Wireless Fitness Apparatus (Model: AST-301, AST-302, AST-303)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: September 10, 2019
Received: September 13, 2019

Dear Cassie Lee:

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,

For Vivek Pinto, PhD
Director (Acting)
DHT5B: Division of Neuromodulation
and Physical Medicine 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182136

Device Name
Intelligent Wireless Fitness Apparatus (Model: AST-301, AST-302, AST-303)

Indications for Use *(Describe)*
Intelligent Wireless Fitness Apparatus is indicated to be used for:
Improvement of abdominal tone, strengthening of the abdominal muscles development of firmer abdomen.
Strengthening, Toning and Firming of buttocks and thighs.

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.

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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: Shenzhen OSTO Technology Co., Ltd.
Establishment Registration Number: Applying
Address: No.43 Longfeng Road, Xinsheng Community, Longgang Street Longgang District, Shenzhen City Guangdong Province, CHINA
Tel: +86-755-29769546
Fax: +86-755-29769540
Contact Person: Li Yang (General Manager)
Email: annaosto@163.com

Application Correspondent:

Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Company Name: Shenzhen OSTO Technology Co., Ltd.
Trade/Device Name: Intelligent Wireless Fitness Apparatus
Model Name: AST-301, AST-302, AST-303
Common Name: Powered Muscle Stimulator
Product Code: NGX
Regulation Number: 21 CFR 890.5850
Regulatory Class: 2

3. Predicate Device Information

Predicate Device 1:
510(K) Number: K131291
Company Name: Johari Digital HealthCare Ltd.
Trade/Device Name: Torc Body
Common Name: Powered Muscle Stimulator
Product Code: NGX
Regulation Number: 21 CFR 890.5850
Regulatory Class: 2

Predicate Device 2:
510(K) Number: K133929
Company Name: Shenzhen OSTO Technology Co., Ltd. Trade
Device Name: Health Expert Electronic Stimulator
Common Name: Electronic Stimulator
Product Code: NUH, NGX
Regulation Number: 882.5890, 890.5850
Regulatory Class: 2

4. Device Description

Intelligent Wireless Fitness Apparatus is indicated to be used for: Improvement of abdominal tone, strengthening of the abdominal muscles development of firmer abdomen. By muscle stimulation, the device helps to strengthen and firm the abdomen, arms and thighs.
The device is including a main unit and 3 kinds of electrode pads. The therapeutic parameters are easily set using the buttons on the device.
There are three buttons on the main unit, On/off button for on/off and mode selection, "+" button and "-" button for level adjustment.
The accessories is electrode pads. The electrode pads connect to the main unit by buttons (which is permanent secured on the main unit and the electrode pad). All the accessories can only be changed by local distributor.

5. Intended Use / Indications for Use

Intelligent Wireless Fitness Apparatus is indicated to be used for:
Improvement of abdominal tone, strengthening of the abdominal muscles development of firmer abdomen.
Strengthening, toning and firming of buttocks and thighs.

6. Test Summary

Intelligent Wireless Fitness Apparatus, Model: AST-301, AST-302, AST-303 had been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Usability test according to IEC 62366 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
- IEC 62133 Edition 2.0 2012-12 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)]

Note:
The materials and manufacturing used for the Intelligent Wireless Fitness Apparatus are identical to those of the predicate device K133929, and the Electrode Pads have been demonstrated to conform with the following biocompatibility standards:

• ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity

• ISO 10993-10: 2009, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Intelligent Wireless Fitness Apparatus 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**	**Predicate Device**	**Remark**
510(k) number	Applying	K131291	K133929	--
Device name	Intelligent Wireless Fitness Apparatus	Torc Body	Health Expert Electronic Stimulator	
Model Name:	AST-301, AST-302,	--	AST-300C and AST-	--

		AST-303		300D	
Company name		Shenzhen OSTO Technology Co., Ltd.	Johari Digital HealthCare Ltd	Shenzhen OSTO Technology Co., Ltd.	
Product Code		NGX	NGX	NUH, NGX	SE
Regulation Number		21 CFR 890.5850	21 CFR 890.5850	882.5890, 890.5850	SE
Indications for Use		Intelligent Wireless Fitness Apparatus is indicated to be used for: Improvement of abdominal tone, strengthening of the abdominal muscles development of firmer abdomen. Strengthening, toning and firming of buttocks and thighs.	Torc Body is indicated to be used for: Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. Strengthening, Toning and Firming of buttocks & thighs.	PMS (Mode 1~8) It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. TENS (Mode 9~25) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.	SE
Primary Function		Muscle stimulation	Muscle stimulation	Muscle stimulation	SE
Principle of Action		Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	SE
Clinical Use		OTC	OTC	OTC	SE
Target area		abdominal muscles, buttocks and thighs	abdominal muscles, buttocks and thighs	abdominal muscles, buttocks thighs and foot	SE
Shape of electrode		Butterfly-shaped, irregular	Butterfly-shaped, irregular	Rectangle, irregular	SE
Method of electrode application		Self-adhesive with belt versus adhesive silicone	Self-adhesive with belt versus adhesive silicone	Self-adhesive with belt versus adhesive silicone, non-adhesive	SE
Power Source(s)		Adapter (Model HDMU05E-050100, HDMU05B-050100, HDMU05U-050100) Input:100-240 Vac; 50/60 Hz; 0,3A; Output: 5 V ; 1A Rechargeable Lithium-ion Battery: 3.7Vdc	24 V DC Battery pack	100 – 240 V AC, 50–60 Hz	SE Note 2
Electrical Protection		Class II, BF	Class II, BF	Class II, BF	SE
-Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage	**NC**	< 0.1μA	--	--	SE
	SFC	0.1mA	--	--	SE

Current					
Number of Output Modes		8	2	25	SE Note 1
Number of Output Channels:		2	--	2	SE
Synchronous or Alternating		Alternating	--	Alternating	SE
Method of Channel Isolation		Voltage Transform Isolation	--	Voltage Transform Isolation	SE
Regulated Current or Regulated Voltage		Voltage Control	Voltage Control	Voltage Control	SE
Software/Firmware/Microprocessor Control		Yes	Yes	Yes	SE
Automatic Overload Trip		No	No	No	SE
Automatic No-Load Trip		No	No	No	SE
Automatic Shut Off		Yes	--	Yes	SE
Patient Override Control		Yes	Yes	Yes	SE
Indicator Display	**On/Off Status**	Yes	--	Yes	SE
	Low Battery	Yes	--	No	SE
	Voltage/ Current Level	Yes		Yes	SE
Timer Range (minutes) (clarify for each mode if different)		15min	1- 60 min	25min	SE Note1
Compliance with Voluntary Standards		Complied with ISO 10993-5, ISO 10993-10, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	Complied with ISO 10993-5, ISO 10993-10, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	Complied with ISO 10993-5, ISO 10993-10, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	SE
Weight		80g (Without accessories)	--	2Kg (Without accessories)	SE Note1
Housing Materials and Construction		Main unit: ABS plastic	--	Main unit: ABS plastic	SE
Waveform (e.g., pulsed monophasic, biphasic)		Pulsed, symmetric, biphasic	--	Pulsed, symmetric, biphasic	SE
Maximum Output Voltage		44V±10% @ 500Ω 80V±10% @ 2kΩ 112V±10% @ 10kΩ	--	44V±10% @ 500Ω 80V±10% @ 2kΩ 112V±10% @ 10kΩ	SE
Maximum Output Current		88mA±10% @ 500Ω 40mA±10% @ 2kΩ 11.2mA±10% @10kΩ	--	88mA±10% @ 500Ω 40mA±10% @ 2kΩ 11.2mA±10% @10kΩ	SE
For multiphasic waveforms only: -		Symmetrical phases	--	Symmetrical phases	SE

Symmetrical phases					
Phase Duration		120µs	290 µs	120 µs	SE
Net Charge (mC per pulse)		10.56 µ C @ 500Ω	--	10.56 µ C @ 500Ω	SE
Maximum Phase Charge, (mC)		12.78 µ C @ 500Ω	35.7 µ C @ 500Ω	12.78 µ C @ 500Ω	SE
Maximum Average Current		1.69mA @ 500Ω	--	1.69mA @ 500Ω	SE
Maximum Current Density, (mA/cm²)		0.026mA/cm² @ 500Ω	0.176mA/cm²	0.026mA/cm² @ 500Ω	SE
Maximum Power Density		16.37 µ W/cm² @ 500Ω	0.0089 W/cm²	16.37 µ W/cm² @ 500Ω	SE
Burst Mode (i.e., pulse trains)	**Pulses per burst**	1	--	1	SE
	Bursts per second	77	--	77	SE
	Burst duration (seconds)	12.94ms	--	12.94ms	SE
	Duty Cycle [Line (b) x Line (c)	240 µ s/12.94ms	--	240 µ s/12.94ms	SE
ON Time (seconds)		3s	--	3s	SE
OFF Time (seconds)		3s	--	3s	SE
Type of Energy		Electrical	Electrical	Electrical	SE
Type of Operation		Continuous	Continuous	Continuous	SE
Pulse Repetition Rate		8.33 Hz	1– 200 Hz	8.33 Hz	SE
Pulse Amplitude		0 – 100%	0 – 100%	0 – 100%	SE
Induced Current in the Tissue		11.2-80 mA	28 mA	11.2-80 mA	SE
Selection of parameters (Intensity)		Yes	Yes	Yes	SE
Shape of Stimulation Pulse		Rectangular, with interphase interval	Symmetrical Biphasic Square Wave	Rectangular, with interphase interval	SE
Energy Source		Adapter (Model HDMU05E-050100, HDMU05B-050100, HDMU05U-050100) Input:100-240 Vac; 50/60 Hz; 0,3A; Output: 5 V ; 1A Rechargeable Lithium-ion Battery: 3.7Vdc	24 V DC Battery pack and Adaptor: 100 – 240 V AC, 50–60 Hz	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	SE Note 2
System Dimensions		Main Unit: 50X37mm Electrode pad for	Main Unit: 152x102x203 mm (6×4×8 in)	428 x428.8 x 185mm	SE Note1

	model AST-301: 198mm x 164mm x 2mm Electrode pad for model AST-302: 192mm x 164mm x 2mm Electrode pad for model AST-303: 125 mm x 80mm x 2mm Each gel sheet 90mm x 60mm x2 mm	Electrodes: Large (50mm) Small (40mmx80mm)	Electrodes: Foot Conductive Rubber: 254mm × 98mm × 13mm, 99.27 cm2 Small: 88mm × 58mm × 3.2mm, 50.04 cm2	
Electrode materials	Transparent PET silicone (Gel sheet)	--	Small Electrode Pads: white silica gel, black conductive silicone, transparent conductive adhesive silicone, transparent PET silicone	SE
Ambient Temperature	0°C to +40°C	0°C to +44°C	5°C to +45°C	SE Note 1
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	SE

Note 1:
Although the “Number of Output Modes”, “Time Range”, “Indicator Display”, “Ambient Temperature”, “Dimensions” and “”weight” are a little difference from the predicate devices, but these are not key parameters which affect safety or effectiveness, so the differences will not raise any safety or effectiveness issue.

Note 2:
Although the “Power Source” and “Energy Source” of subject device are different from predicate devices, but it all comply with IEC 60601-1 and IEC 60601-2-10 requirements, so the differences will not raise any safety or effectiveness issue.

Finial Conclusion:
The subject device “Intelligent Wireless Fitness Apparatus model AST-301, AST-302, AST-303” is Substantial Equivalent to the predicate devices K131291 and K133929.

8. Date of the summary prepared: October 9, 2019