September 6, 2018

Shenzhen OSTO Technology Co., Ltd.
℅ Cecilia Ceng
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, Guangdong 510006 Cn

Re: K172834
Trade/Device Name: Low Frequency Multi Function Physiotherapy Instrument, Models AST-603, AST-2012A, AST-2010B
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: July 25, 2018
Received: August 6, 2018

Dear Cecilia Ceng:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela D. Scott -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172834

Device Name
Low Frequency Multi-Function Physiotherapy Instrument

Indications for Use *(Describe)*
PMS (Mode 1)
It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

TENS (Mode 2)
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.

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.
Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: Low-frequency Multi-function physiotherapy instrument
Common Name: Electronic Stimulator
Classification name:

1. Stimulator, Nerve, Transcutaneous, Over-The-Counter (NUH)
2. Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)

Review Panel: Neurology
Product Code: NUH, NGX
Regulation Class: II
Regulation Number: 21 CFR 882.5890, 890.5850

3. Predicate Device Information

Sponser: Shenzhen OSTO Technology Company Limited
Trade Name: Health Expert Electronic Stimulator
Common Name: Electronic Stimulator
Classification name: Stimulator, Nerve, Transcutaneous, Muscle, Powered, For Muscle Conditioning, Over-The-Counter
510(k)number: K133929
Review Panel: Neurology, Physical Medicine
Product Code: NUH, NGX
Regulation Number: 882.5890, 890.5850
Regulation Class: II

4. Device Description

Low-frequency Multi-function Physiotherapy Instrument is a household multifunctional device. it can stimulate healthy muscles in order to improve and facilitate muscle performance, and to relief the pain associated with sore and aching muscles in the waist, upper and lower back, back of the neck, upper extremities (shoulder, arm and hand), lower extremities (hip, knee, ankle, leg and feet) due to strain from exercise or normal household work activities by applying current to stimulate nerve.
Low-frequency Multi-function Physiotherapy Instrument has 2 operation modes and two channels, which can give certain electrical pulse through 2 pairs of electrode pads on the skin to help users to enjoy body massage and sole massage.
The electronic stimulatory module has the operating elements of ON/OFF Switch, Display screen, Mode Selection key, Intensity Modification keys and time selection keys.
The LCD display screen can show selected mode, output intensity of body and/or sole, and time remaining of an application mode.
The device is equipped with accessories of electrode pads, electrode wire, adapter, remote controller. The electrode wire is used to connect the pads to the main unit; the adapter wire is used to connect the adapter to the device.

5. Intended Use / Indications for Use

PMS (Mode 1)
It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.
TENS (Mode 2)
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.

6. Test Summary

Low-frequency Multi-function physiotherapy instrument, Model: AST-603, AST-2012A, AST-2012B has 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
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10
- 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”
- The waveform test has also been conducted to verify the output specifications of the device according to “Guidance for Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use and Guidance for Powered Muscle Stimulator for Muscle Conditioning”.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Electronic Muscle Stimulator 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	Verdict
Company	Shenzhen OSTO Technology Co., Ltd	Shenzhen OSTO Technology Co., Ltd	--

Elements of Comparison	Subject Device	Predicate Device	Verdict
Trade Name	Low-frequency Multi-functional hysiotherapy instrument	Health Expert Electronic Stimulator	--
Classification Name	Stimulator, Nerve, Transcutaneous, Over-The-Counter	Stimulator, Nerve, Transcutaneous, Over-The-Counter	--
510(k) Number	K172834	K133929	--
Product Code	NUH, NGX	NUH, NGX	SE
Intended Use / Indications for Use	PMS (Mode 1) It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. TENS (Mode 2) 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.	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
Power Source	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	SE
-Method of Line Current Isolation	Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage Current	NC: AC: 54.5μA, DC: 0.5μA SFC: AC:120.0μA, DC: 0.6μA	NC: AC: 54.5μA, DC: 0.5μA SFC: AC:120.0μA, DC: 0.6μA	SE
Main Unit Weight	115 g	2 kg	SE Note 1
Main Unit Dimension	128.6 x 69.8 x 25 mm	428 x 428.8x 185mm	SE Note 1
Number of Output Channels:	2	2	SE
Number of Output Modes	2	25	SE Note 2
Output Intensity Level	99	99	SE

Elements of Comparison		Subject Device	Predicate Device	Verdict
Synchronous or Alternating?		Synchronous	Synchronous	SE
Regulated Current or Regulated Voltage?		Yes	Yes	SE
Software/Firmware/Microprocessor Control?		Yes	Yes	SE
Automatic Shut Off		Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	SE
	Low Battery	No	No	
	Voltage/ Current Level	Yes	Yes	
Timer Range		5-60 min	25 min	SE Note2
Waveform		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	SE
Shape		Rectangular, with interphase interval	Rectangular, with interphase interval	SE
Maximum Output Voltage		44V±10% @ 500Ω	44V±10% @ 500Ω	SE
		80V±10% @ 2KΩ	80V±10% @ 2KΩ	
		112V±10% @ 10KΩ	112V±10% @ 10KΩ	
Maximum Output Current		88mA±10% @ 500Ω	88mA±10% @ 500Ω	SE
		40mA±10% @ 2KΩ	40mA±10% @ 2KΩ	
		11.2mA±10% @ 10KΩ	11.2mA±10% @ 10KΩ	
Pulse Duration		120μs	120μs	SE
Pulse frequency		77.3Hz	77.3Hz	SE
Charge density		0.21μC/ cm² @ 500Ω	0.21μC/ cm² @ 500Ω	SE
Power density		16.37μW/cm² @ 500Ω	16.37μW/cm² @ 500Ω	SE
Active surface area		50.04cm²	50.04cm²	SE
Additional Features				
Environment for operation		Temperature: 5 ~ 45 Humidity: 15% - 90% Atmospheric pressure	Temperature: 5 ~ 45° C Humidity: 20 ~ 65% RH	SE

Elements of Comparison	Subject Device	Predicate Device	Verdict
	range of 700 hPa to 1 060 hPa		
Environment for storage	Temperature: -25 - +70℃ Humidity: up to 90% Atmospheric pressure range of 700 hPa to 1 060 hPa	Temperature: 0 ~ 45° C, Humidity: 10 ~ 90% RH Electrode Pad: 10~20° C	SE
	For pads: Temperature:10~20°C Humidity: up to 90% Atmospheric pressure range of 700 hPa to 1060 hPa	For pads: Temperature:10~20°C Humidity: up to 90% Atmospheric pressure range of 700 hPa to 1 060 hPa	SE

Comparison in Detail(s):

Note 1 (Weight，Dimension):
These data would be different for different devices because the internal circuit design and components choosing are different, which make them have similar difference on weight, dimensions. But weight and dimensions won't affect the safety and effectiveness of the device so it can deemed as the substantially equivalence.

Note 2 (Number of Output Modes, Time Range):
The design of the time range is basing on the intended use. And according to the output specification comparing with the predicated devices, we set the default treatment time is 15min and the user could adjust the levels which could meet the requirements in the energy aspect. Thus, the subject device is actually the same as predicated ones.

Final Conclusion:

The subject device "Low-frequency Multi-function physiotherapy instrument" is Substantial Equivalent to the predicate devices.

8. Date of the summary prepared: July 25, 2018