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

May 17, 2017

Jiangsu Betterlife Medical Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CN

Re: K163094
Trade/Device Name: TinniLogic Mobile Tinnitus Management Device
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: April 14, 2017
Received: April 17, 2017

Dear Diana Hong:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Eric A. Mann -S
2017.05.17 13:21:17 -04'00'

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Mobile Tinnitus Management Device

Models:BTG-A5/ BTG-A6/ BTG-B5/ BTG-B6/ BTG-C5/ BTG-C6

Indications for Use *(Describe)*
The TinniLogic Mobile Tinnitus Management Device is indicated for use in the temporary relief of tinnitus symptoms. The device is a player to play customized sounds and display professional counseling or education to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K163094

1. Date of Preparation: 4/14/2017

2. Sponsor Identification

Jiangsu BetterLife Medical Co., Ltd.
No. 11 Si Hai Road, Changshu Economic and Technological Development Park, Jiangsu Province, 215513, China.

Establishment Registration Number: 3010197022

Contact Person: Mr. Hongwei Xu
Position: Management Representative
Tel: +86-512-52269378
Fax: +86-512-52269366
Email: jerry.xu@goblm.com.cn

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Subject Device

Trade Name: TinniLogic Mobile Tinnitus Management Device
Common Name: Tinnitus Masker
Models: BTG-A5, BTG-A6, BTG-B5, BTG-B6, BTG-C5 and BTG-C6

Regulatory Information

Classification Name: Tinnitus Masker;
Classification: II;
Product Code: KLW;
Regulation Number: 21CFR 874.3400
Review Panel: Ear Nose& Throat;

Indications for Use
The TinniLogic Mobile Tinnitus Management Device is indicated for use in the temporary relief of tinnitus symptoms. The device is a player to play customized sounds and display professional counseling or education to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

Device Description
The TinniLogic Mobile Tinnitus Management Device is a sound player which is designed to assist the qualified healthcare professional in delivering customized sound therapies and professional counseling or education to the patient for treatment. The TinniLogic Mobile Tinnitus Management Device provides idiopathic tinnitus sound treatment based upon sound stimulation during sleeping or waking hours. The TinniLogic Mobile Tinnitus Management Device uses amplitude modulated (SAM) tinnitus pitch matched sounds, narrow-band noise centered at the tinnitus frequency, broad-band noise, pure tone, white noise, natural sounds, relax sounds, and combination of these sounds.

The subject device consists of a tablet, a specialized headset, a charger and a charger cable.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K140845
Product Name: LEVO Tinnitus Masking Software Device

Predicate Device 2
510(k) Number: K111293
Product Name: SoundCure™ Serenade™ Tinnitus Management System

Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

- IEC 60601-1-2: 2014 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- IEC 60601-1:2005+A1:2012 Medical electrical equipment- Part 1: General requirements for basic safety, and essential performance, including the US National Differences
- Output performance testing including the testing of Maximum output, harmonic distortion and Output frequency; additionally, the output performance testing is conducted to demonstrate that the device calibration and the maximum output reamin valid in various settings of three possible volume controls.

6. Clinical Test Conclusion

No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Subject Device	Predicate Device 1 K140845	Predicate Device 2 K111293
Product Code	KLW	KLW	KLW
Regulation Number	21 CFR 874.3400	21CFR 874.3400	21 CFR 874.3400
Indications for Use	The TinniLogic Mobile Tinnitus Management Device is indicated for use in the temporary relief of tinnitus symptoms. The device is a player to play customized sounds and display professional counseling or education to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.	The Levo System is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.	The SoundCure Serenade Tinnitus Treatment System is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.
Components	TinniLogic Mobile Tinnitus Managment Device with software pre-installed Earphones Accessories (adaptor, power cable, USB cable)	Levo Manager software supplied pre-installed on iPad or iPad Air Levo Patient software supplied pre-installed on iPod touch Ear buds Accessories (standard Apple charger with Apple device)	Serenade Treatment Software (to be used with user's commercially available computer) Serenade patient device with software pre-installed Earphones Accessories (power supply, power cord, USB cable)
Sounds	Sounds customized to the patient by qualified healthcare professional. The subject device just only displays the following sounds and	Sounds customized to the patient by qualified health care professional. From 1 to ten (10) combinations of the following sounds:	Sounds customized to the patient by qualified health care professional. Individual patient selectable from the following sounds: Sinusoidal amplitude

	the combination of them: Sinusoidal amplitude modulated (SAM) tinnitus pitch matched sounds Narrow-band noise centered at the tinnitus frequency Broad-band noises Pure tone White noises Natural sounds Relax sounds	Pure Tone White Noises Narrow Band Noises (bandwidth selectable by HCP) Includes the ability to create sinusoidal amplitude modulated (SAM) tones.	modulated (SAM) tones (S-Tones) (choice of 2 predefined by HCP) White Noises Band Noises
Data Logging	Data logging of patient use.	Data logging of patient use.	Data logging of patient use.
Volume Control	Individual volume control per ear of the application software; Physical volume controls	Individual volume control per ear of the application software; Physical volume controls	Individual volume control per ear of the application software; Physical volume controls
Maximum Sound Loudness Output	90 dB SPL	85 dB SPL	92 dB SPL
Sound Output Frequency	50Hz ~15KHz	100Hz- 16KHz	1 KHz to 14 KHz
Power	Rechargeable lithium-Ion (Li-Ion) Battery, external power supply with power cord for recharging	Rechargeable lithium-Ion (Li-Ion) Battery, external power supply with power cord for recharging. (Battery and charger provided by Apple for Apple devices)	Rechargeable lithium-Ion (Li-Ion) Battery, external power supply with power cord for recharging.
Communication	USB cable and/or Wireless	Wireless	USB cable
Patient contact material	Earphones	Earphones	Earphones
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2

The subject device is as safe and effective as the two predicate devices. The subject device has the similar indications for use, technological characteristics as its predicate devices. The subject device and predicate devices have the same target population and audio player functions.

The Maximum sound loudness output and Output sound frequency of the subject device are similar as those of the predicate devices. This minor difference on output performance will not raise new problem on the safety and effectiveness of the subject device. The output performance tests of the subject device have been conducted to demonstrate that the device calibration and the maximum output reamin valid in various settings of three possible volume controls.

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices.