510(k) SUMMARY

JUL 18 2014

Otoharmonics® Levo® System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Otoharmonics Corp
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Portland, Oregon 97204
Phone: 503.336.9906

Contact Person: Michael Baker, President/CEO

Date Prepared: July 11, 2014

Name of Device

Levo System

Common or Usual Name/Classification Name, Classification

Tinnitus Masker Device, 21 CFR 874.3400 (Product Code KLW), Class II

Predicate Devices

SoundCure, Inc.'s Serenade Tinnitus Treatment System (K111293)

Intended Use / Indications for Use

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.

Device Description

The Levo System is designed to assist the qualified health care professional in evaluating the patient's tinnitus and preparing a customized sound therapy to be delivered to the patient during treatment. The Levo System provides idiopathic tinnitus masking treatment based upon sound stimulation during sleeping or waking hours. The Levo System consists of two proprietary software applications that are pre-installed on commercially available, off-the- shelf consumer electronics (i.e., Apple® iPad® or iPad Air™ and iPod®). Custom-fit ear buds are provided with the device. The Levo System uses amplitude modulated tinnitus pitch matched tones, narrow-band noise centered at the tinnitus frequency, and broad-band noise.

Technological Characteristics

The Levo System presents very similar technological characteristics as the predicate Serenade Tinnitus Treatment System in device design and specifications. Both devices are designed to assist in the evaluation of a patient's tinnitus, and can be used by the healthcare professional to prepare a customized sound therapy for each patient. Both devices include software components that operate on designated hardware platforms, although the specific hardware used are not the same (i.e., off-the-shelf consumer electronics versus customized hardware). In addition, the Levo System transmits data wirelessly between the devices, whereas the predicate device

utilizes a USB cord. However, these differences do not raise any new types of safety or effectiveness questions for the Levo device. Robust risk analysis and verification and validation testing further support the substantial equivalence of the devices. In addition, for both devices, the customized sound therapy is delivered to patients through a hand-held audio device. The devices both generate sounds that can be configured from broad band to narrow band, and provide for amplitude modulated tinnitus pitch matched tones. The Levo System can be used to generate the exact same type of amplitude modulated sounds as the predicate device. Therefore, the similar technological characteristics of the devices support substantial equivalence.

Performance Data

Nonclinical testing was conducted to validate the performance of the Levo System and ensure the device performs as intended and meets the design specifications, consistent with FDA's "*Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tinnitus Masker Devices*" (2005). The biocompatibility of the patient-contacting materials of the Levo System has been demonstrated per ISO 10993-1, ISO 10993-5, and ISO 10993-10 for a device with limited duration of contact with intact skin.

Consistent with FDA's guidance document, the Levo System meets the safety performance requirements of AAMI/ANSI ES 60601-1 and electromagnetic compatibility requirements of IEC 60601-1-2.

Software verification and validation testing further demonstrated that the software performs as intended and in accordance with specifications. The potential risks of the Levo System have been identified and evaluated, and the risks were determined to be acceptable, or have been addressed with risk control measures. Performance testing further demonstrated that the acoustic outputs of the device meet specifications, including the following testing:

- Frequency response of the ear buds, patient device, and software
- Amplitude of generated output
- Software/firmware performance
- Amplitude modulation of signal
- Independent volume control of left and right channel of device

Therefore, in all instances of performance testing, the Levo System functioned as intended.

Substantial Equivalence

The Levo System is as safe and effective as the SoundCure predicate device. The Levo System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The Levo System provides the same general types of sounds and amplitude modulated tones as the predicate device. Although the Levo System and the predicate device operate with different patient device hardware, data transmission (i.e., wireless versus USB cable), and output ranges, these minor technological differences between the Levo System and its predicate device do not raise any new issues of safety or effectiveness. Thus, the Levo System is substantially equivalent to the SoundCure

predicate. Further details regarding the comparison of the device and the predicate are providing in the following table.

Trade Name	Otoharmonics Levo System	SoundCure Serenade Tinnitus Treatment System (K111293)
Indications for use	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.
Patient Medium	Hand-held audio device (iPod touch®) for use with custom headphones	Hand-held audio device (Serenade patient device) with headphones
Components	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 health care professional. From 1 to ten (10) combinations of the following sounds: • Pure Tone • White Noises • Narrow Band Noises (bandwidth selectable by HCP) Includes the ability to create sinusoidal amplitude modulated (SAM) tones.	Sounds customized to the patient by qualified health care professional. Individually patient selectable from the following sounds: • Sinusoidal amplitude 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
Volume Control	Individual volume control per ear	Individual volume control per ear
Features in Sleep	Help to Sleep (optional) – Music played to help patient relax	SleepAssist technology – Sleep Mode Timer to help the patient fall asleep
Maximum Output	85 dB SPL	92 dB SPL
Output Frequency	100Hz – 16KHz	1 kHz to 14 kHz
Power	Rechargeable lithium-Ion (Li-Ion) Battery, external power supply (100-250VAC to 5V DC) with power cord for recharging. (Battery and charger provided by Apple® for Apple® devices)	Rechargeable lithium-Ion (Li-Ion) Battery, external power supply (100-250VAC to 5V DC) with power cord for recharging.

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Apple, iPod touch and iPad are registered trademarks of Apple Inc.

Conclusions

In conclusion, the Levo System is substantially equivalent to the SoundCure predicate device and software verification and validation testing further demonstrate that the software performs as intended and in accordance with specifications.

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

July 18, 2014

Otoharmonics
c/o Ms. Yarmela Pavlovic
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K140845
Trade Name: Otoharmonics LEVO Tinnitus Masking Software Device
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus masker
Regulatory Class: Class II,
Product Code: KLW
Dated: June 17, 2014
Received: June 17, 2014

Dear Ms. Pavlovic:

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" (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 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

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

LEVO Tinnitus Masking Software Device

Indications for Use *(Describe)*

The LEVO Tinnitus Masking Device 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ting Zhang -S
2014.07.14 08:58:36 -04'00'

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