October 19, 2017

audiofon USA, Inc.
Jane E. Perrone
V.P. of U.S. Operations
403 Chairman CT., Suite 1
Debary, FL 32713

Re: K171243
Trade/Device Name: audifon Tinnitus-Module
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: September 13, 2017
Received: September 18, 2017

Dear Jane E. Perrone:

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 (DICE) 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 (DICE) 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,

Srinivas Nandkumar -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171243

Device Name
audifon Tinnitus-Module

Indications for Use *(Describe)*
audifon Tinnitus-Module is a tool intended to generate sound as part of a Tinnitus Retraining Therapy (TRT) protocol designed to provide temporary relief for people experiencing tinnitus symptoms. The module can be embedded in a hearing aid.

audifon Tinnitus-Module is intended for adults over 18 years of age.

audifon Tinnitus-Module is targeted for licensed hearing care professionals who are familiar with the evaluation and treatment of tinnitus and hearing losses. The fitting of audifon Tinnitus-Module must be done by a hearing care professional participating in a tinnitus management program.

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."

I. Introduction

1.	**Applicant's Name and Address:**	audifon USA Inc. 403 Chairman Ct., Suite 1 Debary, Florida 32713 PO BOX 531700 USA
2.	**Contact Person:**	Jane E Perrone Phone: 386-6688812
3.	**Trade or Proprietary Name:**	audifon Tinnitus-Module
4.	**Device Common Name / Classification Name:**	Tinnitus Masker (Regulation Number: 21 CFR 874.3400)
5.	**Product Code:**	KLW
6.	**Classification of Device:**	Class II
7.	**Type of 510(k) submission**	Abbreviated 510(k)
8.	**Establishment Registration Number:**	3005384855
9.	**Address of Manufacturing Site:**	audifon GmbH & Co. KG Werner-von-Siemens-Str. 2 D-99625 Kölleda Germany
10.	**Predicate Device Identification:**	K130514 audifon vico TRT devices
11.	**Date of Preparation**	April 02, 2017

II. Indications for Use

audifon Tinnitus-Module is a tool intended to generate sound as part of a Tinnitus Retraining Therapy (TRT) protocol designed to provide temporary relief for people experiencing tinnitus symptoms. The module can be embedded in a hearing aid.

audifon Tinnitus-Module is intended for adults over 18 years of age.

audifon Tinnitus-Module is targeted for licensed hearing care professionals who are familiar with the evaluation and treatment of tinnitus and hearing losses. The fitting of audifon Tinnitus-Module must be done by a hearing care professional participating in a tinnitus management program.

III. Description of Device

The above mentioned audifon Tinnitus module is a digital noise generator which was developed to be used in a tinnitus retraining therapy. This product has up to four different programs, which can be programmed in shape and level to fit the individual user's needs. The programming can be done with a standard HI-PRO and the audifon audifit software. Within the software the amplification of the device can be fitted to the individual needs. The noise can be adjusted in shape with low- and high-cut filters and in the output level. It can be housed in a standard In-the-ear instrument housing, in a standard behind-the-ear instrument housing as well as in standard receiver-in-the ear housing.

IV. Comparison Information to Predicate Device

The mentioned devices are substantially equivalent to the audifon vico TRT devices (K130514). The mentioned devices and the audifon vico TRT devices are fully digital masker, with programmable noises. Within the program the level and the shape of the noise can be adjusted. Also the mentioned devices and the audifon vico TRT devices provide an additional amplification and can be programmed with the fitting software and a standard HI-PRO programming box.
The non-clinical performance data which were measured according to official standards (ANSI S3.22-2014) verify that the devices have a similar effectiveness as the predicate device. For TRT therapy sound level below 80 dB SPL are needed. Level above 80 dB SPL usually not used. Furthermore, as described within the OSHA (29CFR 1910.95) the output level should not exceed 85 dB A. Therefore a warning in the software will occur that higher level should not be used or only in case of a hearing loss. So the lower maximum output has no influence on the effectiveness of the devices.
The frequency range provides an equivalent white noise with the same sound quality.
In conclusion, the non-clinical tests demonstrate that the submitted devices are as safe as effective the predicate device and the performance are as well as the predicate device.
The submission for tinnitus masker relies on a special control that is defined in section 874.3400. The special controls are identical applied as with the predicate device and supports the substantial equivalence.

The following tables compare the submitted devices and the audifon vico TRT devices.

	audifon device with active audifon Tinnitus-Module	**audifon vico TRT family**
Indications For Use	audifon Tinnitus- Module is a tool intended to generate sound as part of a Tinnitus Retraining Therapy (TRT) protocol designed to provide temporary relief for people experiencing tinnitus symptoms. The module can be embedded in a hearing aid. audifon Tinnitus- Module is intended for adults over 18 years of age. audifon Tinnitus- Module is targeted for licensed hearing care professionals who are familiar with the evaluation and treatment of tinnitus and hearing losses. The fitting of audifon Tinnitus-Module must be done by a hearing care professional participating in a tinnitus management program.	The combined devices are intended for persons suffering from a chronic persistent ringing in the ears (Tinnitus) in combination with a mild to moderate hearing loss that is indicated for a hearing aid fitting. The products may be used for masking Tinnitus as part of a Tinnitus Retraining Therapy (TRT) protocol and should be utilized only in consultation with a qualified hearing healthcare professional. The devices provide hearing aid amplification to compensate for the hearing loss as well as broadband noise for immediate distraction or masking of Tinnitus or long term habituation of Tinnitus.
Operation / Mechanism	Uses broadband noise; Manages tinnitus through masking and distraction Circuit type: Digital Programmable: Yes Available noises: Four Volume control: Yes white-noise is adjustable noise level is programmable adjustable Low Battery Indicator programmable Program Switch Tones	Uses broadband noise; Manages tinnitus through masking and distraction Circuit type: Digital Programmable: Yes Available noises: Four Volume control: Yes white-noise is adjustable noise level is programmable adjustable Low Battery Indicator programmable Program Switch Tones
Where Used	May be used anywhere	May be used anywhere
Physical Description	Standard In-the-ear instrument housing Standard behind-the-ear instrument housing Standard receiver-in-the-ear instrument housing	Standard In-the-ear instrument housing Standard behind-the-ear instrument housing

	audifon device with active audifon Tinnitus-Module	audifon vico TRT family
Maximum Output Characteristics	White noise: 100 - 112 dB SPL frequency range: 100 - 8000 Hz	White noise: 107 - 116 dB SPL frequency range: 100 - 8000 Hz
Power Source	standard 10 zinc air 1,4V hearing aid battery standard 312 zinc air 1,4V hearing aid battery standard 13 zinc air 1,4V hearing aid battery	standard 10 zinc air 1,4V hearing aid battery standard 312 zinc air 1,4V hearing aid battery standard 13 zinc air 1,4V hearing aid battery
Quality Assurance Standard	ANSI S3.22-2014 to ensure proper functioning of HA	ANSI S3.22-2014 to ensure proper functioning of HA

V. Conclusion

- The devices have similar operating mechanisms as the predicate device.
- The devices have similar acoustic characteristics as the predicate device.
- The devices are similar in style as the predicate device.
- The devices are similar in intended use as the predicate device
- The devices have the same targeted population as the predicate device