K130417

5 510(k) Summary

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 sueno CIC audifon sueno S audifon sueno T CIC audifon sueno T S
4.	**Device Common Name / Classification Name:**	Tinnitus Masker (Regulation Number: 21 CFR 874.3400)
5.	**Product Code:**	KLW
6.	**Classification of Device:**	Class II for tinnitus masker
7.	**Establishment Registration Number:**	3005384855
8.	**Address of Manufacturing Site:**	audifon GmbH & Co. KG Werner-von-Siemens.Str. 2 D-99625 Kölleda Germany
9.	**Market Device with Substantial Equivalence:**	K091552 audifon switch TRT
10.	**Date of Preparation**	July18, 2013

SEP 12 2013

Indications for Use

The devices are intended for the adult population suffering from a chronic persistent ringing in the ears (Tinnitus), who do not need or desire amplification. 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 licensed hearing healthcare professional, who is trained in subsequent rehabilitation therapy, or a qualified audiologist.

Description of Device

The audifon sueno devices aredigital noise generatorswhich were developed to be used in a tinnitus retraining therapy. These products have one program, 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. The noise can be adjusted in shape with low- and high-cut filters and in the output level. It is housed in a standard In-the-ear instrumenthousing (CIC housing) or in a standard behind-the-ear instrumenthousing (S housing).
The audifon sueno T devices (sueno T S and sueno T CIC) can be additional adjusted with three trimmer potentiometers by the hearing healthcare professional.

Comparison Information to Predicate Device

The audifon sueno devices are substantially equivalent to the audifon switchTRT (K091552). The audifon sueno devices and the audifon switch TRT are fully digital noiser, with programmable noises. Within the program the level and the shape of the noise can be adjusted. Also the audifon sueno devices and the switch TRTcan 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 S3.22-2009) verify that the sueno devices have a similar effectiveness as the predicate device. For TRT therapy only low sound levels below 80 dB SPL are needed. So for an effective TRT system levels above this are not needed. Also according the OSHA (29CFR 1910.95) output levels should not exceed 85 dBA. Therefore a warning in the software will occur that the higher levels 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 noisewith the same sound quality.
In conclusion the non-clinical tests demonstrate that the audifon sueno devices are as safe, as effective, and perform 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 table compares the audifon sueno devices and the audifon switch TRT.

	audifon sueno CIC audifon sueno S audifon sueno T CIC audifon sueno T S	audifon switch TRT
Indication For Use	The devices are intended for the adult population suffering from a chronic persistent ringing in the ears (Tinnitus), who do not need or desire amplification. 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 licensed hearing healthcare professional, who is trained in subsequent rehabilitation therapy, or a qualified audiologist.	The device is addressed to the adult population with a chronic persistent ringing in the ears (Tinnitus), who do not need or desire amplification.It may be used for masking tinnitus as part of tinnitus management program that is prescribed by a licensed hearing healthcare professional, who is trained in subsequent rehabilitation therapy, or a qualified audiologist. Therefore it generates a broadband noise with sufficient bandwidth and intensity and is applied on the ear.
Operation / Mechanism	Uses broadband noise; Manages tinnitus through masking and distraction Circuit type: Digital Programmable: Yes Available noises: One Volume control: Yes white-noise is adjustable noise level is programmable adjustable Low Battery Indicator	Uses broadband noise; Manages tinnitus through masking and distraction Circuit type: Digital Programmable: Yes Available noises: Four Volume control: No 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 (CIChousing) Standard behind-the-ear instrument housing (S housing)	Standard receiver-in-the-ear instrument housing
Maximum Output Characteristics	RMS Output Characteristics: White noise: sueno CIC 70 dB SPL sueno S 92 dB SPL sueno T CIC 71 dB SPL sueno T S 72 dB SPL frequency range: 200 - 8000 Hz	RMS Output Characteristics: White noise: 100 dB SPL frequency range: 200 - 6000 Hz
Power Source	standard 10 zinc air 1,4V hearing aid battery (CIC housing) standard 312 zinc air 1,4V hearing aid battery (S housing)	Uses standard 312 zinc air 1.4V hearing aid battery
Quality Assurance Standard	ANSI S3.22-2009 to ensure proper functioning of HA	ANSI S3.22-2009 to ensure proper functioning of HA

Conclusion

- The sueno devices have similar acoustic characteristics as the predicate device.
- The sueno devices are similar in style (ITE or BTE) as the predicate device.
- The sueno devices are similar in material as the predicate device.
- The sueno devices are similar in intended use as the predicate device
- The sueno devices have the same targeted population as the predicate device

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

September 12, 2013

audifon-USA, Inc.
% Ms. Jane Perrone
V.P. of U.S. Operations
403 Chairman Court, Suite 1
DeBary, FL 32713

Re: K130417
Trade/Device Name: audifon sueno S
audifon sueno CIC
audifon sueno T S
audifon sueno T CIC
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: August 13, 2013
Received: August 14, 2013

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

4 Indications for Use Statement

510(k) Number (if known): K130417

Device Name:	audifon sueno CIC	(TRT noise generator)
	audifon sueno S	(TRT noise generator)
	audifon sueno T CIC	(TRT noise generator)
	audifon sueno T S	(TRT noise generator)

Indications for Use:

The devices are intended for the adult population suffering from a chronic persistent ringing in the ears (Tinnitus), who do not need or desire amplification. 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 licensed hearing healthcare professional, who is trained in subsequent rehabilitation therapy, or a qualified audiologist.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Cherish R. Giusto -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices