510(k) Summary

AUG 12 2009

K091552

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: 386-668-8812
3.	**Trade or Proprietary Name:**	switch 8 TRT
4.	**Device Common Name / Classification Name**	Hearing Aid, Tinnitus Masker
5.	**Product Code**	ESD, KLW
6.	**Classification of Device**	Class I for hearing aid 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**	K003558 Siemens TCI Combi

Description of Device

Device Name: **audifon switch 8 TRT**

The switch 8 TRT is a digital noise generator and hearing aid that was developed to be used in a tinnitus retraining therapy. This product has four different programs, which can be programmed in shape and level to fit the individual users' needs. The programming can be done with a standard HI-PRO and the audifon audifit software. Within the software the amplification of the combi-masker can be fitted to the individual needs. The noise can be adjusted in shape with low-cut and high-cut filters and in the output level. It is housed in a standard receiver-in-the-ear instrument housing.

Indications for Use:

The switch 8 TRT is addressed to the adult population with a chronic persistent ringing in the ears (Tinnitus), who also need or desire amplification. The amplification suits the needs of a mild to a moderate hearing loss. 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.

Comparison Information to Predicate Device

The switch 8 TRT is substantially equivalent to the Siemens TCI Combi (K003558). Both devices are fully digital nosier, with four programmable noises. Within the programs the level and the shape of the noise can be adjusted. Also both devices provide an additional amplification and can be programmed with fitting software and a standard Hi-Pro programming box.

	switch 8 TRT	Siemens TCI Combi
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Indications For Use	chronological persistent ringing in the ears, Tinnitus patients with or without a hearing loss	Tinnitus patients with or without a hearing loss
Target Population	Adults with tinnitus that are participating in a tinnitus management program	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program

Operation / Mechanism	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	Uses broadband noise; Manages tinnitus through masking and distraction Circuit type: Digital Programable: Yes Avaible noises: Four Volume control: Yes Volume Control Range: Programable: OFF, 8 dB, 16 dB, 32 dB
Where Used	May be used anywhere	May be used anywhere
Physical Description	Standard receiver-in-the-ear instrument housing	Standard behind-the-ear instrument housing
Maximum Output Characteristics	RMS Output Characteristics: White noise: 100 dB SPL (maximum output fixed at 80dB) frequency range: 200 - 6000 Hz	RMS Output Characteristics: White noise: 102 dB SPL
Power Source	Uses standard 312 zinc air 1.4V hearing aid battery	Uses standard zinc air 1.4V hearing aid battery
Quality Assurance Standard	ANSI S3.22-2003 to ensure proper functioning of HA	ANSI 3.21-2003 to ensure proper functioning of HA

Information required under Title 21, Section 8743400, and not already provided above

Risks to health

There is no more risk associated with the use of this device than the use of a conventional hearing aid or tinnitus masker, because the device cannot deliver damaging sound intensity. (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposures))

Hearing Healthcare Professional Diagnosis

The sale and fitting of the switch 8 TRT will only be conducted through a Hearing Healthcare Professional, such as an audiologist, hearing aid specialist or otolaryngologists.

Benefits

Relief of tinnitus symptoms may be provided by the switch 8 TRT when utilized with appropriate counselling and tinnitus retraining or masking therapy.

Warnings for Save Use

As this device cannot deliver damaging sound intensity, there is no warning required about sound output level. General use precautions are given in the User's manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUDIFON USA
C/O Jane Perrone
Vice President of U.S. Operations
403 Chairman Court, Suite 1
Debary, FL 32713

AUG 12 2009

Re: K091552
Trade/Device Name: switch TRT and switch 8 TRT
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW, ESD
Dated: May 22, 2009
Received: May 27, 2009

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
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): K091552

Device Name: audifon switch TRT

Indications for Use:

The switch TRT 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.

Prescription Use _____ (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)

James K. Kane, Ph.D

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091552

4. Indications for Use Statement

510(k) Number (if known): K091552

Device Name: audifon switch 8 TRT

Indications for Use:

The switch 8 TRT is addressed to the adult population with a chronic persistent ringing in the ears (Tinnitus), who also need or desire amplification. The amplification suits the needs of a mild to a moderate hearing loss.
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.

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