K083486

5. 510(k) Summary

FEB 19 2009

11. Indications for Use

November 14, 2008

Contact Information:

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Audifon USA Inc.
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386.668.8812

The jump C TRT is addressed to the adult population with a chronological 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.

12. Description of Device

The jump C TRT is an analog noise generator that was developed to be used in a tinnitus retraining therapy. This product has a variable output level and an adjustable low-cut filter for a custom-tailored noise shape, which fits the individual user. It is housed in a standard housing for cymba application.

13. Comparison Information to Predicate Device

The jump C TRT is substantially equivalent to the General Hearing Instruments Tranquil Tri OE (K974751). Both products are analog noisier with no amplification. The jump C TRT differs in the housing for cymba application and in an additional adjustable low-cut filter, so the product can be individualized for every user. A detailed comparison is given in the following table.

	audifon jump C TRT	General Hearing Instruments Tranquil Tri OE
Intended Use	For use in tinnitus retraining therapy and also suitable for masking tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Indications For Use	Tinnitus patients without a hearing loss	
Target Population	Adults with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation / Mechanism	Uses broadband noise; Manages tinnitus through masking and distraction Circuit type: Analog Programmable: No Available noises: One Volume control: Yes adjustable low-cut filter Volume Control Range: 23 dB	Circuit type: Analog Programable: No Availble noises: One Volume control: Yes Volume Control Range: 40 dB
Where Used	May be used anywhere	
Physical Description	Standard housing for cymba application	Custom in-the-ear product
Maximum Output Characteristics	RMS Output Characteristics: White noise: 66 dB SPL frequency range: 200 - 8600 Hz	RMS Output Characteristics: High-tone noise: 75 dB SPL
Power Source	Uses standard 10A zinc air 1.4V hearing aid battery	
Quality Assurance	Measurements following ANSI 3.22-2003 to ensure proper functioning	

14. 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 Exposure))

Hearing Healthcare Professional Diagnosis

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

Benefits

Relief of tinnitus symptoms may be provided by the jump C TRT when utilized with appropriate counselling and tinnitus habituation 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Audifon Hearing Systems
c/o Jane E. Perrone, Vice President of U.S. Operations
403 Chairman CT., Suite 1
Debary, FL 32713

FEB 19 2009

Re: K083488
Trade/Device Name: jump S TRT, jump S+ TRT, jump CIC TRT, jump C TRT
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: II
Product Code: KLW
Dated: January 12, 2009
Received: January 14, 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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, M.D.

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

K083488

4. Indications for Use Statement

510(k) Number (if known): K083488

Device Name: audifon jump S TRT

Indications for Use:

The jump S TRT is addressed to the adult population with a chronological 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 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joan K. Kam Ph.D

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

510(k) Number K083488

K083488

4. Indications for Use Statement

510(k) Number (if known): K083488

Device Name: audifon jump CIC TRT

Indications for Use:

The jump CIC TRT is addressed to the adult population with a chronological 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 ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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. Kamphaus

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

510(k) Number K083488

K083488

4. Indications for Use Statement

510(k) Number (if known): K083488

Device Name: audifon jump C TRT

Indications for Use:

The jump C TRT is addressed to the adult population with a chronological 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 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)

James K. Kan, Ph.D

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

510(k) Number K083488

K083488

4. Indications for Use Statement

510(k) Number (if known): K083488

Device Name: audifon jump S+ TRT

Indications for Use:

The jump S+ TRT is addressed to the adult population with a chronological 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 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)

James K. Randolph

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

510(k) Number K083488