K070599

JUL 13 2007

510K Summary

APPLICANT:	Tinnitus Otosound Products, LLC
ADDRESS:	880 First Street, Suite 403 Los Angeles, CA 90012
CONTACTS:	Geraldine Crean, Ph.D. Regulatory Liaison, Tinnitus Otosound Products, LLC gerldinecrean@yahoo.com 310-927-6151 310-273-8217 Anthony Materna, Ph.D. CEO, Tinnitus Otosound Products, LLC tmaterna@top_llc.net 213-626-0927
DATE OF SUBMISSION:	February 28, 2007
TRADE OR PROPRIETARY NAME:	Customized Sound Therapy
COMMON OR UNUSUAL NAME(S):	CST
CLASSIFICATION NAME:	Tinnitus Masker Device (TMD) Described in 21 CFR 874.3400 Class II, product code KLW

PREDICATE DEVICE(S)

Manufacturer:	Petroff Audio Technologies, Inc.
Tradename:	Dynamic Tinnitus Mitigation System, DTM-6
510K Number:	K974501

Manufacturer:	Neuromonics (formerly TiniTech)
Tradename:	TinniTech ANMP System
510K Number:	K030791

SUBSTANTIAL EQUIVALENCE

Customized Sound Therapy is claiming substantial equivalence to two devices.

1. Equivalence to the Dynamic Tinnitus Mitigation System, DTM-6, manufactured by Petroff Audio Technologies Inc. 510K number K974501.

2. Equivalence is also claimed to the TinniTech ANMP System, manufactured by Neuromonics (formerly TiniTech). 510K number K030791

DEVICE DESCRIPTION

The Tinnitus Otosound Products LLC (TOP-LLC), Customized Sound Therapy (CST), falls under devices described in 21 CFR 874.3400 Class II, product code KLW. The device is a CD comprised of software with two components: a graphic user interface and cmusic program. The software can be used on a notebook or desktop computer with at least Windows XP (SP2) having at least a 1.2 GHz Pentium III CPU (or equivalent), 256 MB of RAM, 1 GB of free disk space, a CD drive, and an available USB port.

The Customized Sound Therapy software produces, and transfers sounds to a sound wave file. This sound file can be stored on any commercially available computer hard drive or portable audio device (PAD) like an iPod.

DESCRIPTION OF DEVICE DESIGN

The CST software consists of specialized programs for creating the CST sounds, which are matched as closely as possible to the tinnitus sensation experienced by the patient. The CST software is based on the cmusic acoustic compiler and a proprietary graphic user interface developed specifically for use during sound matching with CST [1; Chapter 3, pp. 150-214; Appendix D, pp. 490-546]. Under control of a qualified audiologist or other qualified professional, the CST software writes the matching sound on the hard drive of the computer. A copy of this sound is transferred to a commercially available portable audio device for use by the patient during therapy. The volume control on the PAD is used to match that apparent level of the CST sound to the patient's tinnitus sensation as subjectively judged by the patient.

The system is intended to provide relief from the disturbance of tinnitus in an attempt to provide temporary relief of the effect of tinnitus

INTENDED USE

The TOP-LLC CST is intended for use by a qualified healthcare professional such as an otolaryngologist, an audiologist, or other qualified professional. It is intended to mask or intermittently mask the patient's tinnitus as part of a tinnitus management program.

Patients receive a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with CST. Initial hearing and tinnitus tests are conducted by a qualified audiologist familiar with the treatment of tinnitus; subsequent management of the treatment is carried out by an audiologist or other qualified professional.

INDICATIONS FOR USE

The CST system is a CD with software that enables qualified professional to identify, with the patient's verbal input, the sounds that most closely match the patient's tinnitus. The device is indicated to mask and intermittently mask tinnitus as part of a tinnitus management program. The target population for the device is adults (18 years and over) who present with tinnitus, that may or may not be accompanied with hearing loss at the higher frequencies, and who are participating in a tinnitus management program.

RISKS AND WARNINGS FOR SAFE USE

The software packaging and the CD are clearly marked with two warnings; 1) the sounds on the discs should not be played at uncomfortable levels, and 2) the CST system should not be used if such use prevents the user from hearing sounds warning of danger (like the beeping of oncoming vehicles).

The following caution statement is also on the software packaging and the CD:

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of this device.

DEVICE CHARACTERISTICS

The CST device consists of computer software, which identifies, produces and transfers custom sounds, CST, from a desktop or laptop to a PAD. The CST software is based on the cmusic acoustic compiler (standard in generating computer music) that includes a proprietary graphic user interface developed specifically for use during sound matching with CST [1]. CST software will be use with standard computer and audio equipment that is commercially available. The standard commercially available components are intended for use as designated by the manufacturer.

CONCLUSIONS

CST is equivalent to tinnitus masking devices already approved for marketing.

REFERENCES

[1] Moore, F. R. *Elements of Computer Music* (Prentice-Hall, 1990)

[2} Folmer, R.L. Long-term reductions in tinnitus severity. BMC Ear, Nose, and Throat Disorders, 2002, 2(3): 1-9.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

Tinnitus Otosound Products, LLC
c/o Geraldine Crean, Ph.D.
880 First Street, Suite 403
Los Angeles, CA 90012

Re: K070599
Trade/Device Name: Customized Sound Therapy (CST)
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus masker
Regulatory Class: Class II
Product Code: KLW
Dated: May 22, 2007
Received: May 24, 2007

Dear Dr. Crean:

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, MD

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

K070599

Indications for Use

510(k) Number: [redacted] K070599

Device Name: Customized Sound Therapy (CST)

Indicaitons For Use:

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Perscription Use: __X__ AND/OR Over-The Counter Use____

(Part 21 CFR 801 Subpart D) (12 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Drug Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

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

510(k) Number K070599