K112752

DEC 16 2011

5 510(k) Summary

Company Name:	ANM Adaptive Neuromodulation GmbH
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Contact person:	Dr. Ingrid Rohm Quality & Regulatory Manager
Date summary prepared:	September 9, 2011
Classification Name/ Common Name:	Tinnitus Masker
Trade Name:	ANM T30 CR® Tinnitus Therapy System
Product Code:	KLW
Device Classification:	Class II
Predicate Devices:	Neuromonics Tinnitus Treatment System, K043274 (Neuromonics PTY Ltd.) TinniTech ANMP System, K030791 (Tinnitech Ltd.)

Device Description:
The ANM T30 CR® is a computer-controlled system for tinnitus therapy. The therapy is provided to the patient by individualized, ambient acoustic tones. The system consists of four components:

ANM T30 CR® Programmer (computer) including the tinnitus analysis software ANM T30 CR® SW:
The ANM T30 CR® Software is used to measure the tinnitus, adjust the individual therapeutic stimulation signals and program the patient device (ANM T30 CR® Stimulator).

ANM T30 CR® Patient Console:
The ANM T30 CR® Patient Console is connected to the ANM T30 CR® Programmer and is used by the patient to adjust the parameters specific to his/her tinnitus (frequency and loudness) during tinnitus measurement and stimulation signal adjustment.

ANM T30 CR® Stimulator (patient device):
The stimulator is used by the patient for the application of the therapeutic stimulation signal. It has a rechargeable battery for the energy supply and electronic components to generate the stimulation signal.

ANM T30 CR® Earphones:
The ANM T30 CR® Earphones are to be connected either to the ANMT30 CR® Patient Console to measure the tinnitus and adjust the stimulation signal or to the ANM T30 CR® Stimulator to apply the stimulation signal.
Patient contact parts are manufactured from materials that meet the ISO-10993 biocompatibility requirement contact with intact skin, as tested by their suppliers. The ANM T30 CR® Tinnitus Therapy System meets the applicable general electrical safety requirements of IEC 60601 1, and the requirements of IEC 60601-1-2.

Intended Use:
The ANM T30 CR® Tinnitus Therapy System is intended to provide relief from the disturbance of tinnitus while using the system, and with regular use (over several months) may provide relief to the patient when not using the system.
The ANM T30 CR® Stimulator is a patient device for home use.
The ANM T30 CR® Stimulator is fitted and programmed by a qualified healthcare professional familiar with tinnitus treatment.

Stimulation needs to be applied for several hours a day over a period of weeks or months.
The target population is adults over 18 years of age.

Table 5.1: Comparison to Predicate Device:

	ANM T30 CR® System	**Neuromonics Tinnitus Treatment System**	**TinniTech ANMP System**
Intended use	The ANM T30 CR® Tinnitus Therapy System is intended to provide relief from the disturbance of tinnitus while using the system, and with regular use (over several months) may provide relief to the patient when not using the system. The ANM T30 CR® Stimulator is a patient device for home use. The ANM T30 CR® Stimulator is fitted and programmed by a qualified healthcare professional familiar with tinnitus treatment. Stimulation needs to be applied for several hours a day over a period of weeks or months. The target population is adults over 18 years of age.	The Neuromonics Tinnitus Treatment System is intended to provide relief from the disturbance of tinnitus while using the system, and with regular use (over several months) may provide relief to the patient when not using the system. The Neuromonics Tinnitus Treatment System is intended to interact and intermittently interact with the patients tinnitus as part of a tinnitus management program. The addition of the music is to aid the promotion of relaxation during the tinnitus interaction process. The initial hearing and tinnitus tests are conducted by a qualified audiologist familiar with the treatment of tinnitus; the subsequent management of the treatment is carried out by an appropriate healthcare	The ANMP System is intended to completely mask and intermittently mask tinnitus as part of a tinnitus management program. The addition of the music is to aid the promotion of relaxation during the tinnitus masking process. The initial hearing and tinnitus tests are conducted by a qualified audiologist familiar with he treatment of tinnitus; the subsequent management of the treatment is carried out by an appropriate healthcare professional. 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

	ANM T30 CR® System	Neuromonics Tinnitus Treatment System	TinniTech ANMP System
		professional. 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.	management program.
Physical dimensions	ANM T30 CR® Stimulator (1.85" x 1.65" x 0.91") with preprogrammed auditory stimuli delivered through earphones	iPod-like device (4.06" x 2.32" x 0.71") with prerecorded audio stimuli delivered through headphones	The Philips eXanium 401 mini MP3 mini CD player with earphones is supplied by TinniTech Size: 3.6" x 4.7" x 1.1" (LxHxD)
Maximum Output Characteristics	Maximum output is 80 dB(A) (software-controlled). This maximum can be exceeded only with the consent of a qualified healthcare professional to 115 dB(A). As this maximum output exceeds the OSHA (Standard 1910.95) 8 hour time weighted average for the occupational workplace, warnings are included in the User Manual	Fixed at 80 dB SPL	The maximum output from the earphones could exceed 85 dBA, the OSHA (Standard 29CFR 1910.95) 8 hour time weighted average for the occupational workplace, and therefore a warning about setting the player volume setting at a comfortable (safe) level is included in the User's Manual and on the player
Frequency Range	90 Hz – 13 kHz	100 Hz - 12.5 kHz	20 Hz – 20 KHz
Audio Signal Technology	Digital	Digital	Digital
Medium	Flash Memory	SD Memory Card	Two mini CDs
Energy used	2.4V, 2 x rechargeable Ni-MH button, 1.2V	Lithium polymer, output 6V	The supplied mini disc player, the Philips eXpanium 401 operates from either one AA cell or a 110 VAC mains adapter provided with the player
Transducer (headphones type)	Use only earphones supplied with the ANM T30 CR® Tinnitus Therapy System. The volume of the	Use only earphones supplied with the Neuromonics device. Other earphones may not transmit the prescribed	Use the earphones provided with the mini disc player

	ANM T30 CR® System	Neuromonics Tinnitus Treatment System	TinniTech ANMP System
	stimulation sequence program has been acoustically aligned specifically for use with these earphones	sounds that are essential for treatment	
Where used	Home use under the supervision of a qualified healthcare professional	Home use under the supervision of a qualified clinician	Home use under the management of an appropriate qualified healthcare professional
Safety	Avoid using the ANM T30 CR® Tinnitus Therapy System while driving or other activities that require the patient's full attention	Avoid using the Neuromonics device while driving, cycling, or while performing any other activity that requires the patient's full attention	The ANMP therapy should never be undertaken when tinnitus masking sounds might prevent the patient from hearing cues or warnings of likely harm or danger

Summary of performance data:
Nonclinical verification and validation testing activities were conducted to establish the performance, functionality and reliability characteristics of the device. Testing involved verification of software requirement specifications from risk analysis. The testing shows that the ANM T30 CR® System is as safe, as effective and performs as well as or better than the predicate devices identified in the above Comparison Table.

Risks to health
With a maximum output of 115 dB(A) the ANM T30 CR® Stimulator could exceed the occupational workplace OSHA standard 29 CFR 1910.95. To avoid possible hearing damage the health care professional only can program the stimulator to allow for acoustic signals above 80 dB(A) for use by tinnitus patients who suffer from impaired hearing.
The User's Manual carries precautions to reduce the acoustic volume or stop the treatment if the auditory stimulation volume is uncomfortable. It also states that stimulation should not been done when undisturbed attention is required.

Hearing Healthcare Professional Diagnosis
The sale and fitting of the ANM T30 CR® system will only be conducted through a Hearing Healthcare Professional.

Benefits
Supported by appropriate counselling and/or tinnitus therapy, relief from tinnitus symptoms may be experienced by using the ANM T30 CR® Stimulator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ANM Adaptive Neuromodulation GmbH
c/o Dr. Ingrid Rohm
Quality & Regulatory Manager
Im Mediapark 6d
50670 Cologne
Germany

DEC 16 2011

Re: K112752
Trade/Device Name: ANM T30 CR® Tinnitus Therapy System
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: September 9, 2011
Received: September 21, 2011

Dear Dr. Rohm:

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 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 (301) 796-7100 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

K112752

4 Indications for Use

510(k) Number (if known):

Device Name: ANM T30 CR® Tinnitus Therapy System

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Prescription Use ___X____ 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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James K. Kane Ph.D.
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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