K030791

APR 17 2003

510(k) SUMMARY

TinniTech ANMP System

Applicant:	TinniTech Ltd Level 2, 55 Market Street Sydney NSW 2000 Australia Phone: +61 2 9283 0601 Fax: +61 2 9283 0602
Date of Submission:	28 February 2003
Manufacturing Site:	ResMed Ltd. 97 Waterloo Road North Ryde NSW 2113 Australia
Establishment Registration Number:	8020057
Distributor:	Mr R West, Go West, Inc. 2502 Tournament Court Castle Rock, CO 80104 Phone/Fax: (303) 663-8089
Contact Name for Submission:	Lachlan James (contact address as per Applicant)
Trade or Proprietary Name	ANMP (Acoustic Neuro Modulation Protocol)
Common or Usual Names	Tinnitus Masker
Classification Name (FDA)	KLW : Masker Tinnitus
Classification	Class II device
Reason for Submission	New Device

Indications for Use:

The TinniTech ANMP System comprises two (2) mini compact disks that have been prerecorded with selected relaxation music and other sounds spectrally adapted to suit the particular patient's hearing thresholds. The device is indicated to 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 spectral adaptation of the sound is determined by the patient's audiogram measured by a qualified audiologist; the patient's tinnitus therapy is managed by an appropriate healthcare professional. The target population for the device is adults (18 years of age and over) who present with tinnitus that may or may not be accompanied with hearing loss at the higher frequencies.

Intended use

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 the treatment of tinnitus; the subsequent management of the treatment is carried out by an appropriate healthcare professional.

Target population

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.

Device description

The TinniTech ANMP system consists of:

One CD pre-recorded in the MP3 format with selected relaxation music and superimposed low amplitude, wide spectrum noise that is spectrally adapted to compensate for the individual patient's higher frequencies hearing loss. This CD is intended for the complete masking of tinnitus.

One CD pre-recorded in the MP3 format with selected relaxation music that is spectrally adapted to compensate for the individual patient's higher frequencies hearing loss however this CD has been recorded such that the dynamic characteristics of the sound allow the tinnitus to intermittently break through during the quieter passages of the recorded music.

A commercially available, battery powered, stereo, MP3 mini compact disc player with earphones with a performance specification that TinniTech has tested and shown to be suitable for the delivery of the ANMP treatment sounds or waveforms. At this time Tinnitech will supply the Phillips eXpanium 401™ MP3 mini compact disc player. Other suitable players will be offered as TinniTech tests and approves them for the ANMP System.

Substantial equivalence

TenniTech is claiming substantial equivalence to two devices:

Equivalence is claimed to the Dynamic Tinnitus Mitigation System, DTM-6 manufactured by Petroff Audio Technologies Inc. 510k number; K974501

Equivalence is also claimed to the Custom TCI Instrument manufactured by Siemens Hearing Instruments, 510k number; K011364.

K974501

The Dynamic Tinnitus Mitigation System, DTM-6 manufactured by Petroff Audio Technologies Inc. 510k number; K974501 is a four (4) CD set system capable of being played on any commercial CD player with headphones or speakers. CD#1 provides digital tinnitus masking sounds only, CDs #2, #3 and #4 provide digital tinnitus masking sounds plus relaxation messages, alpha rhythms (a gentle musical sound generated on electronic musical instruments), music and/or nature sounds. CDs #2, #3 and #4 add the indication of promoting relaxation during the tinnitus masking process to the indication of providing 'temporary relief of tinnitus symptoms'.

Like the predicate device K974501 the TinniTech ANMP sounds are recorded on mini CDs (in the MP3 format) capable of being played on any one of a number of good quality, portable MP3 mini disc players, the patient using appropriate earphones to listen to the sound recorded on the discs.

The TinniTech ANMP, like CDs #2, #3 and #4 of the predicate device includes on CD1 digital tinnitus masking sounds together with selected musical sounds to promote relaxation during the tinnitus continuous masking process.

K011364

The Custom TCI Instrument manufactured by Siemens Hearing Instruments, 510k number: K011364, is a fully digital, low level noise generator. The device is programmable, with selected noise and output levels and is indicated for use in the delivery of tinnitus habituation and tinnitus masking therapies.

The output noise in the Custom TCI Instrument can be custom-tailored to the user's individual requirements.

Like the predicate device, K011364, the TinniTech ANMP custom-tailors the sounds on both CD 1 and CD 2 to suit the individual patients' hearing requirements. This is achieved analysing the patient's audiogram and boosting the amplitude of those sounds or tones where the patient has been shown to have a reduced hearing threshold.

The TinniTech ANMP also includes on CD 2 specially selected music with a dynamic characteristic that allows the patient's tinnitus sound to intermittently break through the masking effect of the music. This function, like the predicate device K011364, assists in enhancing the patient's habituation to the tinnitus sound.

Table of Comparisons

Characteristic	New Device	Predicate Device K974501	Predicate Device K011364
Intended Use	Continuously and intermittently mask tinnitus as part of a tinnitus management program with masking noise and selected music to promote the relaxation of the patient during the delivery of the Tinnitech ANMP therapy.	Temporary relief of tinnitus symptoms and the promotion of relaxation during the tinnitus masking process.	Continuously mask and partially mask tinnitus as part of a tinnitus management program.
Target Population	Adults (18 years and over), both with and without high frequency loss, with tinnitus who are participating in a tinnitus management program.	All tinnitus sufferers, including that percentage of severe sufferers who are "un-maskable" through the application of a masking sound.	Adults and children (over 5 years of age) with tinnitus who are participating in a tinnitus
Operation			
Audio signal technology	Digital	Digital	Digital
Available noises/sounds	Pre-adapted to the patient's hearing characteristics, a wide selection of musical sounds incorporating Tinnitus Masking noise (20Hz – 20KHz) digitally recorded on mini compact discs in MP3 format.	Proprietary dynamic formats of sounds incorporating Dynamic Tinnitus Mitigation technology (20Hz – 20KHz) recorded on digital storage means that are played at audible levels.	Programmable noise spectrum with pre-selection of four noise types digitally stored in solid state memory.
Medium	Two mini CDs (but could be expanded by providing a variety of music on additional discs).	Four CDs/audio tapes	Solid state memory.

Characteristic	New Device	Predicate Device K974501	Predicate Device K011364
Operation – continued Volume control	Yes, user controlled with warning in the User Instruction Manual stating "To prevent the possible damage to your hearing the volume setting of the disc player should not be set at levels where you are uncomfortable with the sound".	Yes, user controlled with a note stating that the volume should always be set at a low level when first trying any CD.	Yes, user controlled within limits pre-programmed by the managing health professional.
Distribution	To be sold via direct and indirect channels involving an appropriately qualified healthcare professional.	Currently sold and supported via mail order.	The sale and fitting of the Siemens Custon TCI will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.
Components	The components of the complete TinniTech ANMP system include: • Sound files on storage means (digital mini CDs) • A high quality, digital MP3 mini CD player, of normal commercial supply • User's Manual	The components of the complete predicate device system include: • Sound files on storage means (digital CDs or Audio tapes) • A digital CD or Audio Tape player, either portable or fixed of normal commercial supply or pre-existing in the home or car. User's Manual (called Workbook)	The Siemens Custom TCI is a fully digital, programmable, low level noise generator that is available in a full in-the-ear, half shell, in-the-canal, or helix shell. User's Manual.

Characteristic	New Device	Predicate Device K974501	Predicate Device K011364
Audio player device.	The Philips eXpanium 401 mini MP3 mini CD player with earphones is supplied by TinniTech Size 3.6"L x 4.7" H x 1.1" D Weight: 200 g (7.1 ounces) Battery: 1 x 1.5V AA Accessories: Earphone	A standard Walkman type digital player or equivalent player is a commonly used listening/delivery device. The Sony model CDFV-15 is recommended. Size: 5.5" x 5.0" x 7/8" Weight: 105 g (3.6 ounces) Battery: 2 x 1.5V AA Accessories: headphones	Not applicable.
Energy delivered	The supplied mini disc player, the Philips eXpanium 401 has a maximum power output per channel of 5mW. 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	No Maximum stipulated or controlled. A home stereo system could be capable of more than 200 Watts output.	Maximum output is 86dBA which exceeds the OSHA (Standard 29CFR 1910.95) 8 hour time weighted average for the occupational workplace therefore warnings are included in the User's Manual.
Characteristic	New Device	Predicate Device K974501	Predicate Device K011364
Energy used	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.	The audio player will utilise mains voltage (1110 VAC) or battery voltage (typically up to 9 VDC)	Small hearing aid type battery.

Characteristic	New Device	Predicate Device K974501	Predicate Device K011364
Transducer (headphones type)	Use the earphones provided with the mini disc player.	Recommended to use either Radio Shack headphones PRO-35 or Sony premium *headphones or* earbuds.	The Siemens Custom TCI is an "in-the –ear" device and is available in four versions: *full in-the-ear, half* shell, in the canal, or helix shell.
Where used	Home use under the management of an appropriately qualified healthcare professional	Home use	Home use
Safety	The ANMP therapy should never be undertaken when the tinnitus masking sounds might prevent the patient from *hearing cues or* warnings of likely harm or danger.	External low-level noise may not be heard due to the fact that the soundwaves are played at audible levels to suppress Tinnitus	
Materials	Typical audio product materials such as plastic and diecast metals.	Typical audio product materials such as plastic and diecast metals.	Typical hearing aid product materials such as plastics.
Performance	The TinniTech ANMP system enables the user to determine whether the delivered therapy assists in the management of their tinnitus.	The predicate device enables the user to determine whether the sound therapy assists them manage their tinnitus	The predicate device enables the end user to determine whether the sound therapy assists them to suppress Tinnitus.
Instructions	The TinniTech ANMP System comes with a User's Guide	The predicate device comes with a 23 page Workbook	

Treatment management and diagnosis

The TinniTech ANMP System is for home use under the direction of an appropriately qualified healthcare professional such as an otolaryngologist, an audiologist, or a licensed hearing aid dealer.

Patients should 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 the TinniTech ANMP treatment.

Risks and warnings for safe use

The maximum output could exceed the occupational workplace OSHA standard 29CFR 1910.95 of 85 dBA. To avoid possible hearing damage the CD player and the User's Manual carry warnings stating that the sounds on the discs should not be played at uncomfortable volume levels.

The CD player carries a label warning against use of the ANMP system if such use prevents the user from hearing sounds warning of danger.

Benefits

Relief from the effects of tinnitus may be provided by the TinniTech ANMP system when used within a tinnitus management program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2003

TinniTech Ltd
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Sydney NSW 2000
Australia

Re: K030791
Trade/Device Name: ANMP (Acoustic Neuro Modulation Protocol)
Regulation Number: 21 CFR §874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: February 28, 2003
Received: March 12, 2003

Dear Mr. James:

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 Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.2 Indications for Use

510(k) Number (if known): K030791

Device Name: TinniTech ANMP System:

Indications for Use:

The TinniTech ANMP System comprises two (2) mini compact disks and a portable, stereo, MP3 mini compact disc player with earphones. The discs have been prerecorded with selected relaxation music and other sounds spectrally adjusted to suit the particular patient's spectral hearing thresholds as shown by their audiogram. The sounds on the discs are reproduced by the mini compact disc player and delivered to the ears by the earphones supplied with the player. The device is indicated for adult (18 years and over) tinnitus sufferers who may or may not suffer higher frequencies hearing loss and are participating in a tinnitus management program.

The TinniTech ANMP System is for home use under the direction of an appropriately qualified healthcare professional such as an otolaryngologist, an audiologist, or a licensed hearing aid dealer.

Patients should 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 non-medical tinnitus management.

The Tinnitech ANMP System may be used to completely mask and intermittently mask tinnitus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

James K. Kane, PhD.
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

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