JUL 2 4 2003

510(K) SUMMARY FOR K031624

1. Sponsor

Daniel S. J. Choy, M.D.
Chairman

Tinnitus Control, Inc.
170 East 77th Street
New York, New York 10021

2. Device Name

Trade Name of Device	Tinnitus Rx
Common Name	Tinnitus Masker
Classification name	Tinnitus Masker
Product Code	KLW
Regulation Class	II
Regulation Number	§874.3400

3. Indications for Use

The Tinnitus Rx consists of a personalized sound recorded onto a compact disc (CD) that can be played on commercially available players and listened to through commercially available headphones. The recorded sound is equivalent to that generated by a qualified hearing healthcare professional who has followed the treatment regimen utilized in the clinical study (provided in the 510(k)). 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 Tinnitus Rx is for home use under the direction of an appropriately qualified healthcare professional.

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 Tinnitus Rx is intended for the temporary relief of tinnitus symptoms.

4. Device Description

The Tinnitus Rx consists of a personalized sound recorded onto a compact disc (CD) that can be played on any commercially available player and listened to through commercially available headphones or speakers.

5. Basis for Substantial Equivalence

The Tinnitus Rx is substantially equivalent to the TTCGHI-T and TTCTM-3 tinnitus maskers, devices cleared under K982451 and the TinniTech ANMP device cleared under K030791. All of the devices use sound to temporarily relieve a patient's tinnitus. Since the Tinnitus Rx utilizes a custom sound for each patient as opposed to a generic broadband sound, a clinical study showing that the device relieves tinnitus was included in the submission. A comparison table to the ANMP device is provided below.

Comparison of Tinnitus Rx and TTCGHI-T / TTCTM3-T

Characteristic	Tinnitus Rx	TinniTech ANMP System
Intended Use	Provide temporary relief of tinnitus symptoms	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 delivery of the Tinnitech ANMP therapy
Target Population	Adults (18 years and over) both with and without high frequency loss, with tinnitus who are participating in a tinnitus management program	Adults (18 years and over) both with and without high frequency loss, with tinnitus who are participating in a tinnitus management program

Operation		
Audio signal technology	Digital	Digital
Available noises/sounds	A personalized sound matching the pitch of the patient's tinnitus derived by following a scientifically studied clinical protocol	Pre-adapted to the patient's hearing characteristics. A wide selection of musical sounds incorporating Tinnitus Masking noise (20Hz – 20 kHz) digitally recorded on mini compact discs in MP3 format.
Medium	One CD	Two mini CDs
Volume Control	Patient labeling warns patient against playing the CD at a level louder than his/her tinnitus	Warning in manual against playing CDs at uncomfortable levels
Distribution	The sale of the custom-made Tinnitus Rx CD will only be through a qualified healthcare professional	Sold via direct and indirect channels involving an appropriately qualified healthcare professional
Components	The components of the Tinnitus Rx include: • Customized CD • User Manual for physician • Patient labeling	The components of the complete TinniTech ANMO system include: • Sound files on storage (mini CDs) • MP3 mini CD player • User Manual
Equipment used	• A commercially available CD player that is capable of producing the sounds generated from the customized CD (Aiwa XP-R232 recommended). • Headphones with a frequency range of 30	• Philips eXpanium 401 mini-disc player with headphones.

	– 20000 HZ and an impedance > 24 ohms.	
Characteristic	New device	Predicate device (K030791)
Where used	Home use under an appropriately qualified healthcare professional	Home use under an appropriately qualified healthcare professional
Safety	The Tinnitus RX is to be used in a quiet environment. The patient is instructed to use the Tinnitus Rx at levels no louder than his/her own tinnitus.	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.
Performance	The pre-CD evaluations at the physician's office provides the patient with a benchmark of the effect he/she should experience with the at-home CD.	The TinniTech ANMP system enables the user to determine whether the delivered therapy assists in the management of their tinnitus.
Instructions	The Tinnitus Rx comes with both physician and patient instruction guides.	The TinniTech ANMP System comes with a User's Guide.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tinnitus Control, Inc.
c/o Dr. Daniel S.J. Choy
170 East 77th Street
New York, NY 10021

Re: K031624
Trade/Device Name: Tinnitus Rx
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: May 22, 2003
Received: June 5, 2003

Dear Dr. Choy:

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

Indications for Use

510(k) Number (if known): K031624
Device Name: Tinnitus Rx

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The Tinnitus Rx is intended for the temporary relief of tinnitus symptoms.

James K. Kane, Ph.D.

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

510(k) Number K031624