MAY 7 1999

K982451

Tinnitus Treatment Centers INCORPORATED

Premarket Notification [510 (k)] Summary

Applicant's/Submitter's Name/Address:	**Tinnitus Treatment Centers, Inc.** **8215 Westchester, Suite 150** **Dallas, TX 75225**
Contact Person:	**David W. Holmes, Ph.D.**
Telephone/Fax:	**800-871-4327 voice** **214-373-7451 fax**
Date of Summary:	**July 10, 1998**

Device Name:

Trade Names: TTCGHI-T and TTCTM3-T

Common Name: Tape Recorded Noise

Classification Name: Tinnitus Masking

Registration Number: None Assigned (submitted and pending)

Classification: Class III, Tier 2

Panel: Ear, Nose and Throat 874.3400

Product Code: 77KLW

Performance Standards: Substantial Equivalence to:

K964216 (Starkey TM-3, TM-5 High Frequency Masker)

K974501 (Digital Tinnitus Masking System)

K963838 (Starkey TM Air Conduction Tinnitus Masker)

K791790 (Starkey TM-5 Behind Ear Tinnitus Masker)

K974751 (General Hearing Inst. Tranquil Tinnitus Masker)

Description of Device

The noise used in the Tinnitus Adaptation Therapy program is a broad-band noise that has been recorded onto a standard audio cassette and can be played on any commercially available audio cassette player and listened to through any commercially available headphones or speakers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 7 1999

David W. Holmes, Ph.D.
President
Tinnitus Treatment Centers Inc.
8215 Westchester Suite 150
Dallas, TX 75225

Re: K982451
Tinnitus Maskers (Model: TTCGHI-T and TTCTM3-T)
Dated: July 10, 1998
Received: July 15, 1998
Regulatory class: III
21 874.3400/Procode: 77 KLW

Dear Dr. Holmes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K982451

DEVICE NAME: Tinnitus Masker, Models TTLGH1-T, TTC-TM3-T-T

INDICATIONS FOR USE:

The noise used in the Tinnitus Adaptation Therapy program is a broad-band noise that has been recorded onto a standard audio cassette and can be played on any commercially available audio-cassette player and listened to through any commercially available headphones or speakers. The noise is used as an adjunct to assist individuals with tinnitus to learn to refocus their attention away from their tinnitus and towards an alternate sound such as the recorded noise. The level of the noise should be adjusted by the individual to a level below their tinnitus so that both the noise and the tinnitus can be heard simultaneously. However, if the individual wishes to completely "mask-out" the tinnitus then the noise could be adjusted so that the noise is louder than the tinnitus.

The other audio tapes in the Tinnitus Adaptation Therapy program consist of relaxation exercises and cognitive retraining lessons to further assist the individual with tinnitus to learn to refocus their attention away from their tinnitus.

The noise and the relaxation/cognitive tapes, when used in a comprehensive tinnitus adaptation therapy program, are indicated for the temporary relief of tinnitus symptoms and the promotion of relaxation during the tinnitus adaptation process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982451

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