JAN 25 1999

K982432

Device Names:

Trade Names: C2007M, C2008M, CE2000, Wonder Ear Masker, Mini Wonder Ear Masker, Wonder Ear Masker/Hearing Aid, PT-2SM, PT-3SM, PT-3LFM, PT-3HFM, PT-3CM, PT-5SM, PT-5LFM, PT-5HFM, and PT-5CM.

Common Name: Tinnitus Maskers

Classification Name: Tinnitus Masking

Registration Number: None Assigned

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)

K9774751 (General Hearing Inst. Tranquil Tinnitus Masker)

Description of Devices:

The tinnitus maskers are broad-band white noise signal generators. They are housed in a variety of hearing aid-type shell configurations that can then be worn either in-the-ear or behind-the-ear. In some instances, canal size permitting, the tinnitus masker circuit can also fit inside a hearing aid shell allowing the patient to benefit from amplified hearing while masking their tinnitus.

Intended Use of Device

The tinnitus masking 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.

Technological Characteristics of Devices

The results of a recent study (Holmes and Jordan, 1998) comparing several tinnitus maskers, including the C2008M, indicated that those tinnitus maskers, which contained mostly high-frequency energy, were unable to be heard by individuals with a high-frequency hearing loss. Five tinnitus maskers were used in the study. Over 80 subjects listened the various noises emitted from the devices and judged the noise on a five-point scale from "very annoying" to "very soothing". The Puretone Limited C2008M was judged equivalent to all of the tinnitus maskers on this judgement scale. The variety of frequency responses among various circuits has the added advantage of assisting those individuals, who have a variety of hearing losses, in being able to hear the noise generated by different circuits.

In the same study, Holmes and Jordan (1998) found that almost all of the devices evaluated were judged by over 80 individuals to be relatively equivalent in their perception of the noise as either "annoying" or "soothing".

Conclusions:

1. All of the PMN tinnitus masking devices have similar acoustic spectral characteristics as the approved devices.

2. All of the PMN tinnitus masking devices are similar in style (ITE or BTE) as the approved devices.

3. All of the PMN tinnitus masking devices are similar in material as the approved devices.

4. All of the PMN tinnitus masking devices are similar in intended use as the approved devices.

5. All of the PMN tinnitus masking devices are similar in style (ITE or BTE) as the approved devices.

6. All of the PMN tinnitus masking devices have the same targeted population as the approved devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 1999

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

Re: K982432
Tinnitus Masker/Hearing Aids, Models: Desktop/Pillow Masker, C2007M, C2008M, CE2000 Masker, Wonder Ear Masker, Mini Wonder Ear Masker, PT-2SM, PT-3SM PT-3CM, PT-3LFM, PT-3HFM, PT-5SM, PT-5CM, PT-5LFM PT-5HFM and Wonder Masker Hearing Aid
Dated: July 13, 1998
Received: July 13, 1998
Regulatory class: III
21 CFR 874.3400/Procode: 77 KLW
21 CFR 874.3300/Procode: 77 ESD

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): K982432

DEVICE NAME: Tinnitus Masker/Hearing Aids

INDICATIONS FOR USE:

Models:

Tinnitus Maskers: Desktop/Pillow Masker, C2007M, C2008M, CE2000 Masker, Wonder Ear Masker, Mini Wonder Ear Masker, PT-2 SM, PT3-SM, PT3- LFM, PT3- HFM, PT5 -SM, PT5- LFM, PT5- HFM.

Tinnitus Maskers with Compatible Hearing Aid Circuitry:

Wonder Ear Masker/Hearing Aid, PT3- CM, PT5- CM

These combination tinnitus maskers and hearing aid devices can be used by people who not only have tinnitus, but who also have a hearing impairment. These devices will be sold in compliance with CFR 801.420 and 801.421 and will include additional labeling for hearing aids.

The noise is a broad-band white noise signal that can be housed in a variety of In-The-Ear or Behind-The-Ear (hearing aid type) shells. The noise can be 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 noise generated from the tinnitus devices. 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. These same tinnitus masking devices can also be used by individuals who desire to mask out ambient environmental noise (e.g. office noise, outside noise, snoring, and other obtrusive noises).

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Restricted Device
Per 874.420 and 421
Hearing Aid

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982432