K013253/S1

APR - 5 2002

510(k) SUMMARY

Hearing Innovations Incorporated HiSonic-TRD

Name and Address of Submitter

Arthur S. Przybyl
President and CEO
Hearing Innovations Incorporated
9040 S. Rita Road Suite 2250
Tucson, Arizona 85747

Phone: 520-663-0544
Facsimile: 520-663-0018

Date Prepared: March 11, 2002

Name of Device and Name/Address of Sponsor

HiSonic-TRD

Hearing Innovations Incorporated
9040 S. Rita Road Suite 2250
Tucson, Arizona 85747

Phone: 520-663-0544
Facsimile: 520-663-0018

Contact Person: Arthur S. Przybyl
President and CEO

Common or Usual Name

Bone Conduction Tinnitus Relief Device

Classification Name

Tinnitus Masker

Predicate Devices

K9638381 Starkey TM Air Conduction Tinnitus Masker, Starkey Labs
K791790 Starkey TM-5 Behind Ear Tinnitus Masker, Starkey Labs
K981704 Aurex-3 Tinnitus Masker, ADM-Tronics Unlimited, Inc.
K951678 HiSonic Hearing Instrument, Hearing Innovations Incorporated

Intended Use

The HiSonic-TRD tinnitus masker is a wearable behind-the-ear style ultrasonic, bone conducted broadband noise and/or sweep frequency stimuli noise generator intended to generate noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. The HiSonic-TRD is intended to be used by those individuals who experience tinnitus, and do not need or desire amplification. The intended use of the HiSonic-TRD includes it's fitting by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapies. The target population is the adult population over 18 years of age. This product is not intended for use in children under the age of 18.

Technological Characteristics and Substantial Equivalence

The HiSonic-TRD generates ultrasound energy and couples the energy to the mastoid bone in order to activate the auditory nervous system, and produce auditory sensations that mask tinnitus. The device consists of a generator/amplifier unit, a piezoelectric transducer, and a headband to hold the transducer firmly against the mastoid bone. The bone conducted energy coupling of the HiSonic-TRD device is substantially similar to that used by two of the predicate devices (ADM-Tronic's Aurex-3; HiSonic Hearing Instrument). The HiSonic-TRD device produces auditory sensations that are substantially similar in effectiveness to that of the predicate tinnitus maskers (the Starkey Labs TM and TM-5 and the Aurex-3).

A 7.2V Lithium Ion battery powers the device. The tranducer is a piezoelectric ceramic that transmits ultrasonic energy in a typical operating frequency bandwidth of 19.5kHz-25.8kHz to the user. The generator/amplifier unit is worn on the body and houses the lithium ion battery. In addition, the body worn unit has an "on/off" switch, a noise/sweep selector switch and a volume control wheel for use by the patient. Both broadband noise and sweep frequency stimuli are incorporated in the device as masking stimuli.

The HiSonic-TRD generates and amplifies electronic oscillations, and then converts them into ultrasound energy with a piezoelectric ceramic transducer. The ultrasound energy is emitted as a broadband noise or as a sweep frequency.

The **HiSonic-TRD** is substantially equivalent to the other currently marketed **tinnitus maskers** that are referenced above. The **HiSonic-TRD** and three of the predicate devices are all tinnitus maskers. In addition, the Company's own 510(k) for an ultrasonic hearing instrument (K951678) supports equivalence of the HiSonic-TRD with regard to the piezoelectric ceramic transducer used to generate the ultrasound. Thus, the **HiSonic-TRD** raises no new issues of safety or effectiveness.

Performance Data

The company has conducted several safety and efficacy studies.

The University of Illinois Bioacoustics Research Laboratory measured the ultrasound energy emitted by the HiSonic-TRD at maximum output power levels against known injury mechanisms. The output intensity data were calculated against a standard thermal model supported by theoretical and experimental studies on blood and intact tissues. The ultrasound energy has been shown to be too low to produce thermal damage and too low to produce any other known damaging bio-effects. The output satisfies the safety limits of IEC 61689.

In a separate study, the University of Illinois Bioacoustics Research Laboratory, performed calibration measurements on the company's HiSonic-TRD device. The results of the calibration measurements demonstrated that

the device is calibrated and that due to the low level of acoustic intensity (mw/cm^2)*, output power, generated by the HiSonic-TRD device that it is not possible to reach unsafe acoustic intensity output levels with the device, even at the highest possible setting on the volume wheel.

*The measured output of acoustic devices intended for use in the audiology market is specified in dbSPL (decibels, sound pressure level) for air-borne devices and bone conducted auditory devices. If the available national or international measurement standards were applied to the HiSonic-TRD device, the output data would be misleading. The company provides exposure data in terms of fundamental physical principles. The output of the device is quantified in terms of the temporal-average acoustic power. The unit of measure is the watt. The acoustic power is then normalized to the area of the transducer element; the area is $1.27cm^2$. The ratio of acoustic power to area is defined as acoustic intensity. $Watts/cm^2$=Acoustic intensity. Due to the low level of output power generated by the HiSonic-TRD the acoustic intensity is reported in milliwatts per cm^2 (mw/cm^2).

A safety study was conducted using eleven human subjects at the University at Buffalo Speech-Language and Hearing Clinic. Subjects ranged in age from 22-70 years, six females and five males. Subjects had normal hearing, hearing loss, tinnitus and no tinnitus present. The study was conducted to examine any changes in auditory thresholds, speech intelligibility and any extra-auditory effects that might occur when using the HiSonic-TRD device. The results demonstrated that there were no significant changes in threshold, there was no decrease in speech discrimination and no interference with speech understanding. With the exception of headaches reported in two subjects the study reported no adverse events as a result of patient use of the device. The safety of the HiSonic-TRD is comparable to the safety of the predicates.

An efficacy study was conducted using twenty human subjects at the Oregon Health Sciences University Tinnitus Clinic. The study was conducted to evaluate the ability of HiSonic-TRD devices to produce clinically useful masking of tinnitus and to determine the effect of any aftereffects. The selection criteria required that each subject's tinnitus was present for at least twelve months and that the tinnitus showed little variability in loudness, localization or sound quality. Baseline air-conduction sound thresholds were measured across the audible range of hearing on all subjects prior to tinnitus

assessment. The HiSonic-TRD device was evaluated using a threshold approach to audibility. The dynamic range (threshold to uncomfortable level) was measured and then the masking effects were assessed. The data obtained from this study indicate that the ultrasound emitted by the device is audible and produces effective masking in patients with clinically significant tinnitus. All subjects were easily able to hear the HiSonic-TRD masking sound (both sweep frequency tones and narrow band noise). The rate of masking achieved with the HiSonic-TRD device was similar to or slightly exceeded the rate of masking observed with FDA cleared tinnitus maskers. In addition, the study demonstrated a lack of interference with the patient's ability to hear ambient sounds during tinnitus masking. The study showed no adverse events as a result of patient use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hearing Innovations, Inc.
c/o Arthur S. Przybyl
President and CEO
9040 S. Rita Road, Suite 2250
Tucson, Arizona 85747

APR - 5 2002

Re: K013253/S001
Trade/Device Name: HiSonic-TRD Tinnitus Relief Device
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: March 6, 2002
Received: March 7, 2002

Dear Mr. Przybyl:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

Indications for Use Form

510(k) Number (if known): K013253

Device Name: HiSonic®-TRD Tinnitus Masker

Indications for Use: The HiSonic-TRD tinnitus masker is a wearable behind-the-ear style ultrasonic, bone conducted broadband noise and/or sweep frequency stimuli noise generator intended to generate noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. The HiSonic-TRD is intended to be used by those individuals who experience tinnitus, and do not need or desire amplification. The intended use of the HiSonic-TRD includes it's fitting by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapies. The target population is the adult population over 18 years of age. This product is not intended for use in children under the age of 18.

(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 C.F.R. 801.109)

(Optional Format 1-2-96)

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

510(k) Number K013253/S001