K070648

JUN 2 9 2007

510 (k) Summary

Applicant's/Submitter's Name/Address: **Melmedtronics, Inc.**
1550 Norwood Dr., Suite 100
Hurst, TX 76054

Contact Person: **David W. Holmes, Ph.D.**

Telephone/Fax: **817-268-1564 voice**
817-285-6182 fax
email: holmes@melmedtronics.com

Date of Summary: **March 5, 2007**

Device Name:

Trade Name:	The Inhibitor™
Common Name:	Tinnitus Masking Device
Classification Name:	Ultra Sonic Tinnitus Masker

Registration Number: None Assigned

Regulatory Class: Class II

Regulation Number: 21 CFR 874.3400

Product Code: 77KLW

Performance Standards: **Substantial Equivalence to the following predicate devices:**

K013253 (Hearing Innovations HiSonic TDR Tinnitus Relief Device)

K021202 (Sound Technique Systems, LLC: Ultra Quiet)
K964216 (Starkey TM-3, TM-5 High Frequency Tinnitus Masker, Starkey Labs)

K003559 (Siemens TCI Tinnitus Control Instrument)

Description of Device

The Inhibitor™ is a hand-held device that emits a ultrasonic signal in the range of 20 – 60 kHz (depending on the resonant frequency of the Piezo element used). It is powered by a 3.6 V Lithium ion rechargeable battery. The transducer is a piezoelectric element. The acoustic output is <100 mW/cm2 and is similar to the Predicate Device Hearing Innovations TRD ultrasound tinnitus masker (K01235) and Sound Technique Systems, UltraQuiet (K021202). Both of these devices use ultrasound. It is also substantially

equivalent to the Starkey TM-3 & TM-5 High Frequency Tinnitus Masker (K964216) and the Siemens TCI Tinnitus Control Instrument (K003559), as both mask and inhibit tinnitus.

Intended Use of Device

The device is intended to be used for the **temporary** relief of tinnitus. Some individuals who used the device reported that their tinnitus went completely away, others found that the loudness of their tinnitus was reduced and some reported no effect. The benefit of treatment varied considerably from one individual to another. The length of time ranged from several minutes, to hours, days and in some cases, lasted as long as weeks. There does not appear to be any common denominator that can be used to predict who will receive benefit or how long the benefit will last. However, in all cases, the benefit was **temporary** and their tinnitus eventually returned to the pre-treatment level.

This is a **medical device** and should only be used with the advice of a physician, audiologist or licensed hearing aid dispenser. This device should only be dispensed to adults 18 years and older. It is **NOT** intended for children.
The following precautions should also be followed:

DISCONTINUE USE (IF CURENTLY USING) OR DO NOT BEGIN TO USE IF:

- **You have a pacemaker.**
- **You are pregnant.**
- **You have any bonded metal teeth retainers.**
- **You have any metal implants in your head or neck.**
- **You are prone to migraines or headaches.**
- **You have had any recent surgeries (last six months) and are still recovering.**
- **You have any thrombosis.**
- **Your tinnitus becomes louder.**
- **You get a headache after using the device.**
- **You become nauseous after using the device.**
- **You notice any discomfort at the treatment site.**
- **You have any medical condition that your physician would advise against its use.**

Technological Characteristics of Device

The Inhibitor^{TM} is a hand-held device that emits a ultrasonic signal in the range of 20 – 60 kHz (depending on the resonant frequency of the Piezo element used). It is powered by 3.6 V lithium ion rechargeable battery. The transducer is a piezoelectric element. The acoustic output is <100 mW/cm2 and is similar to the Predicate Device Hearing Innovations TRD ultrasound tinnitus masker (K01235) and Sound Technique Systems, UltraQuiet (K021202). Both of these devices use ultrasound. It is also substantially equivalent to the Starkey TM-3 & TM-5 High Frequency Tinnitus Masker (K964216) and the Siemens TCI Tinnitus Control Instrument (K003559), as both mask and inhibit tinnitus. Numerous studies have demonstrated the hearing Innovations device to be both safe and effective. Thus, The Inhibitor raises no new issues of safety or effectiveness.

Clinical Studies

The University of Illinois Bioacoustics Research Laboratory (9) 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 was 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 usually intended for use in the Audiology market is typically specified in dB SPL (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 mWatts per cm^2 (mW/cm^2).

New Device (The Inhibitor)

The new device (The Inhibitor) is substantially equivalent to the predicate device. It has an equivalent surface area, depending on the transducer used ($1.27cm^2 - 2.82cm^2$). Any of the values between these sizes would still result in such low power as to be well below any unsafe acoustic intensity output level.
The Hearing & Balance Research Center in Hurst, Texas conducted several clinical trials over a three year period (2004 to 2006) (2,3,4,5,6,7,). They compared several ultrasonic devices that generated different ultrasonic frequencies (broadband noise, sweep frequencies, single frequencies ranging from 19 to 60 kHz) and found similar results among all of the units evaluated.

Procedures

- Each participant signed an Informed Consent.
- Each was given a full audiological evaluation.
- Patient held the device to their mastoid for one minute and then the device was removed.
- Patients rated their tinnitus loudness on a 1 – 10 scale before and after treatment.
- Some patients repeated the treatment as many as four times during one session.
- Temperature reading were taken at the treatment site (mastoid) before and after treatment.

- Hearing was evaluated on 14 ears after 16 (one minute) treatments in a 1.5 to 6.5 hour time period.

Conclusion

The Inhibitor is both safe and effective and is substantially equivalent to the predicate devices cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Melmedtronics, Inc.
c/o David W. Holmes, Ph.D.
1550 Norwood Dr. Suite 100
Hurst, TX 76054

JUN 29 2007

Re: K070648
Trade/Device Name: The Inhibitor
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: April 11, 2007
Received: April 13, 2007

Dear Dr. Holmes:

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.

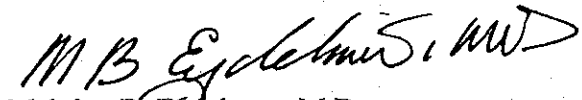
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070648

Indications for Use

510(k) Number (if known): **K070648**

Device Name: **The Inhibitor**

The device is intended to be used for the **temporary** relief of tinnitus. The unit emits an ultrasonic signal that masks or inhibits the sound of tinnitus in many afflicted individuals. The tip of the device is placed firmly against the bone behind the ear and held in place until the device goes off (60-90 seconds).

This is a **medical device** and should only be used with the advice of a physician, audiologist or licensed hearing aid dispenser. Only adults 18 years of age and older should be dispensed an instrument. The following precautions should also be followed:

DISCONTINUE USE (IF CURENTLY USING) OR DO NOT BEGIN TO USE IF:

1. **You have a pacemaker.**
2. **You are pregnant.**
3. **You have any metal bonded teeth retainers.**
4. **You have any metal implants in your head or neck.**
5. **You are prone to migraines or headaches.**
6. **You have had any recent surgeries (last six months) and are still recovering.**
7. **You have any thrombosis.**
8. **Your tinnitus becomes louder.**
9. **You get a headache after using the device.**
10. **You become nauseous after using the device.**
11. **You notice any discomfort at the treatment site.**
12. **You have any medical condition that your physician would advise against its use.**

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070648

Prescription Use X
(Per 21 CFR 801.109)