K021202

JUL 1 3 2002

Attachment 7

510(k) SUMMARY

Sound Technique Systems, LLC: UltraQuiet™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Sound Technique Systems, LLC
710 Denbigh Boulevard, Suite 2C
Newport News, VA 23608

Phone: (757) 833-6794
Facsimile: (757) 833-7406

Contact Person: Martin Lenhardt

Date Prepared: March 27, 2002

Name of Device and Name/Address of Sponsor

UltraQuiet™

Sound Technique Systems, LLC
710 Denbigh Boulevard, Suite 2C
Newport News, VA 23608

Common or Usual Name

Tinnitus Masker

Classification Name

Tinnitus Masker
Product Code: KLW

Predicate Devices

K003559	Siemens TCI Tinnitus Control Instrument
K981704	ADM Tronics Aurex-3 tinnitus masker
K964216	Starkey TM-3, TM-5 High Frequency Tinnitus Masker
K982451	TTC's GHI-T & TN3-T-T tinnitus masker

Intended Use

The UltraQuiet™ device is intended for use in the treatment and control of tinnitus. It consists of a low-level amplifier that converts pre-recorded sound into bone-conducted masking noise that is applied to the mastoid region of the head through a behind-the-ear transducer. The UltraQuiet™ device produces sound of sufficient intensity and bandwidth to mask tinnitus. This device is used in conjunction with diagnosis and therapy by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy. UltraQuiet™ is indicated for the treatment of tinnitus in individuals over 18 years of age that report tinnitus.

Technological Characteristics and Substantial Equivalence

The UltraQuiet™ consists of (1) a compact disc (CD) with recorded sound or an MP3 player, (2) an audio amplifier with AC adapter power supply, and (3) a headband/bone-conduction transducer assembly.

The Company's UltraQuiet™ device covered by this submission is substantially equivalent to other legally marketed tinnitus maskers. Specifically, the UltraQuiet™ device is substantially equivalent to Siemens' Tinnitus Control Instrument (TCI) (K003559), ADM Tronics' Aurex-3 Tinnitus Masker (K9817040), Starkey Laboratories' Starkey TM-3, TM-5 High Frequency Tinnitus Masker (K964216), and the Tinnitus Treatment Centers' TTCGHI- and TTCTN3-T-T devices (K982452).

UltraQuiet™ has the same general intended use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices (K003559, K981704, K964216 and K982452). The UltraQuiet™ device and its predicate devices are all tinnitus maskers. The UltraQuiet™ is functionally equivalent to the Siemens' TCI (K003559) in that it provides broadband masking sound at a similar level of intensity (<76 dB SPL equivalent). It is functionally equivalent to the Aurex-3 (K9817040) in that it delivers the masking sound through bone conduction via the mastoid. It is functionally equivalent to Starkey's TM-3, TM-5 (K964216) because the masking sound included

is tunable (1 kHz - 15 kHz) and provides high frequencies in the audible range (≤15 kHz). Finally, UltraQuiet™ is functionally equivalent to the Tinnitus Treatment Centers' tinnitus masker (K982452) because both devices use recorded noise (the former on a CD and the latter on an audio cassette).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2002

Hogan & Hartson L.L.P.
c/o Howard M. Holstein
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: K021202
Trade/Device Name: UltraQuiet™
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: April 15, 2002
Received: April 16, 2002

Dear Mr. Holstein:

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

Attachment 8

Indications for Use Statement

Applicant: Sound Technique Systems, LLC

510(k) Number (if known): not yet assigned

Device Name: UltraQuiet™

The UltraQuiet™ device is intended for use in the treatment and control of tinnitus. It consists of a low-level amplifier that converts pre-recorded sound into bone-conducted masking noise that is applied to the mastoid region of the head through a behind-the-ear transducer. The UltraQuiet™ device produces sound of sufficient intensity and bandwidth to mask tinnitus. This device is used in conjunction with diagnosis and therapy by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy. UltraQuiet™ is indicated for the treatment of tinnitus in individuals over 18 years of age that report tinnitus.

Sign-Off)
...thalmic Ear,
...vises

510(k) Number K021202

Prescription Use ✓
(Per 21 CFR 801.109)