510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

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San Jose, CA 95128
Phone: (408) 938-5745
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B. Contact Person

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C. Date Prepared

May 5, 2011

D. Device Name

Trade Name:	SoundCure™ Serenade™ Tinnitus Treatment System
Common Name:	Tinnitus Masker
Classification Name:	Tinnitus Masker (21 CFR §874.3400, Product Code KLW)

E. Predicate Devices

The SoundCure™ Serenade™ Tinnitus Treatment System is substantially equivalent to the GN Resound A/S Tinnitus Sound Generator Module cleared under K073636.

F. Device Description

The Serenade System is a personalized sound therapy system designed specifically to evaluate a patient's tinnitus, to create customized audio stimulus, and to deliver and monitor/data log the audio stimulus. The Serenade System is intended to provide relief from the debilitating effects of tinnitus through the use of a hand-held customized digital audio device (Serenade Patient Device) that generates sound therapy/masking. The Serenade System uses modulated tinnitus pitch matched tones (S-Tones) and narrow-band noise centered at the tinnitus frequency and provides broad-band noise. The Serenade System consists of the following components: Serenade Treatment Software, Earphones, Serenade Patient Device as well as the following Accessories: power supply, power cord and USB cable (provided separately).

G. Indications For Use

The SoundCure Serenade Tinnitus Treatment System is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older).

This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

H. Technological Comparison

The Serenade System has similar features as compared to the predicate devices in the table below.

Manufacturer	GN Resound A/S	SoundCure, Inc.
Device Name	TSG Module	SoundCure™ Serenade™ Tinnitus Treatment System
510(k) Number	K073636	K111293
Indications for Use	The Tinnitus Sound Generator Module is a tool to generate sounds to be used in a tinnitus management program to relieve patients suffering from tinnitus. The target population is primarily the adult population over 18 years of age. This product may also be used with children 5 years of age or older.	The SoundCure™ Serenade™ Tinnitus Treatment System is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older).

Manufacturer	GN Resound A/S	SoundCure, Inc.
Device Name	TSG Module	SoundCure™ Serenade™ Tinnitus Treatment System
510(k) Number	K073636	K111293
	The Tinnitus Sound Generator module is targeted for healthcare professionals, which are treating patients suffering from tinnitus, as well as conventional hearing disorders. The fitting of the Tinnitus Sound generator module must be done by hearing professional participating in a tinnitus management program.	This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.
Mechanism of Action	Uses noise that can be configured from broad band to narrow band customized to the patient. Stimulus can be amplitude modulated Level of sound can be adjusted by a user volume control Independent volume parameters per ear (inherent to ear specific device) Stimulus designed to be placed in the background and ignored	Uses noise that can be configured from broad band to narrow band, and pure tones customized to the patient Stimulus can be amplitude modulated Level of sound can be adjusted by a user volume control Independent volume parameters per ear Stimulus designed to be placed in the background and ignored
Maximum Output Characteristics	Maximum output fixed at 93dB SPL Output Frequency Response: Cutoffs at 500-6000 Hz	Maximum output fixed at 92dB SPL Output Frequency Response: 1 kHz to 14 kHz
Target Anatomy	Ear	Ear
Design Features	Tinnitus Sound Generator with frequency shaping Environmental Steering™ Amplitude modulation	Patient Device Sound Generator with frequency shaped sounds Sleep Mode Timer (60 min timer to shut-off when button is pressed) Amplitude modulation

Manufacturer	GN Resound A/S	SoundCure, Inc.
Device Name	**TSG Module**	**SoundCure™ Serenade™ Tinnitus Treatment System**
510(k) Number	**K073636**	**K111293**
	Sounds customized to the patient Behind the Ear 4 sound programs/tracks Data logging of patient use Independent volume control per ear (inherent with individual devices per ear)	Sounds customized to the patient Handheld device with earphones 4 sound programs / tracks (memory for up to 8) Data logging of patient use Individual volume control per ear
Patient Contact Materials	Silicone domes in open configuration	Silicone earphones
Power	Battery, Hearing Aid Battery Size 13	Rechargeable Lithium-Ion (Li-Ion) Battery Serenade System also includes an external power supply (100-250VAC to 5V DC) with power cord for recharging
Meets Applicable IEC60601-1 testing	Yes	Yes

The subject Serenade Patient Device and predicate device are both battery-powered devices worn in the patient's ear. The Serenade Patient Device is equipped with a power supply to recharge the battery and replacement batteries are used with the predicate device. The subject Serenade Patient Device is a hand-held device with earphones while the predicate device is a behind the ear hearing aid style device. Both the subject and predicate device produce individually customizable sounds designed to provide relief to patients suffering from tinnitus. Both the subject and predicate device use software driven applications to allow the healthcare professional to perform the hearing evaluations and to program the devices to produce the customizable sounds.

The technological characteristics and principals of operation of the Serenade System are substantially equivalent to the named predicate device.

I. Summary of Non-Clinical Data

The Serenade System performance characteristics were evaluated in the following in-vitro bench studies:

- System Output Performance Testing
- Operational and Storage Temperature and Humidity Testing
- Packaging Validation Testing
- Battery Useful Life
- Electrical Safety & Electromagnetic Compatibility Packaging Testing
- Hardware Verification
- Software Verification and Validation

Results of the non-clinical testing demonstrate that the materials chosen, the manufacturing process, and design of the Serenade System meet the established specifications necessary for consistent performance during its intended use. In addition, the testing demonstrates the Serenade System is substantially equivalent to the named predicate.

J. Summary of Data

The Serenade System has been carefully compared to a legally marketed device with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the Serenade System performs as intended and meets the design specifications. The non-clinical performance testing and comparison to the predicate device demonstrate that the Serenade System is substantially equivalent to the predicate device and does not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SoundCure, Inc.
c/o Ms. Nancy Lince
Clinical and Regulatory Affairs Consultant
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Suite 500
San Jose, CA 95128

AUG 2 4 2011

Re: K111293
Trade/Device Name: Serenade Tinnitus Treatment System
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: July 13, 2011
Received: July 14, 2011

Dear Ms. Lince:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Indications for Use Statement

510(k) Number (if known): K111293

Device Name: SoundCure™ Serenade™ Tinnitus Treatment System

Indications for Use:

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This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

Prescription Use X **OR** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K111293