K073636

510(k) SUMMARY

MAR 13 2008

SUBMITTER:	GN Resound A/S Lars Hagander
DATE PREPARED:	10 December, 2007
DEVICE NAME:	TSG Module
CLASSIFICATION NAMES:	Tinnitus masker
CLASSIFICATION CODE:	KLW
PREDICATE DEVICEs:	Quiescence and Siemens TCI-Combi

Device Description:

The Tinnitus Sound Generator provides a means for healthcare professionals to create a hearing instrument solution that provide relief for tinnitus patients. This software solution is embedded into a digital hearing instrument platform, so that the end-user can wear this device all day in all environments. The fitting of the digital device containing the Tinnitus sound generator module is fitted by a healthcare professional to fit the exact needs of the tinnitus patient.

Predicate Devices:

Quiescence K040330
Siemens TCI-Combi K003558

Intended 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.

Summary of Non-Clinical Tests:

The tinnitus sound generator is providing means to help tinnitus patients under the Tinnitus Retraining Therapy program (TRT). The philosophy behind this, is not to provide a high masking sound of the tinnitus perceived by the end-user, thereby causing implication of the performance of the end-user speech perception thresholds, but to provide them means to shift emphasis from the tinnitus dominantly perceived at low sound pressure levels, or when in quiet environments. It the assumption that the tinnitus patients are not bothered significantly by their perceived tinnitus, when exposed to other sound stimuli originating from the environment. The functionality of the tinnitus sound generator is fulfilling its purpose, as providing means of shifting tinnitus emphasis, when in quiet environment.
This treatment is done in combination with counselling done by the healthcare professional.

Other:

Pedriatic use precautions
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. However, children and physically or mentally challenged users will require training by a doctor, audiologists, hearing care practitioner or the guardian for the insertion and removal of the device containing the TSG module.
Children and physically or mentally challenged users will require guardian supervision while wearing the device.
The volume control is an optional feature in the TSG module used for adjusting the sound generator output level. To prevent unintended usage by pediatric or physically or mentally challenged users, the volume control must, if enabled, be configured to only provide a decrease of the sound generator output level.

Conclusions:

Testing performed on the TSG Module indicates that they are safe, effective, and perform as well as the predicate devices, when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GN ReSound A/S
c/o Lars Hagander
Lautrupbjerg 9
DK-2750 Ballerup
Denmark

MAR 13 2008

Re: K073636
Trade/Device Name: Tinnitus Sound Generator Module (TSG Module)
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus masker
Regulatory Class: Class II
Product Code: KLW
Dated: December 20, 2007
Received: December 26, 2007

Dear Mr. Hagander:

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.

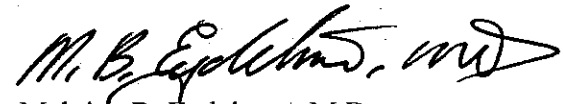
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

K073636

Indications for Use

510(k) Number (if known): K073636

Device Name: TSG Module

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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 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.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shulamith Pang

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

510(k) Number K073636

Prescription Use X
(Per 21 CFR 801.109)