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510(k) Summary – Number: K132965

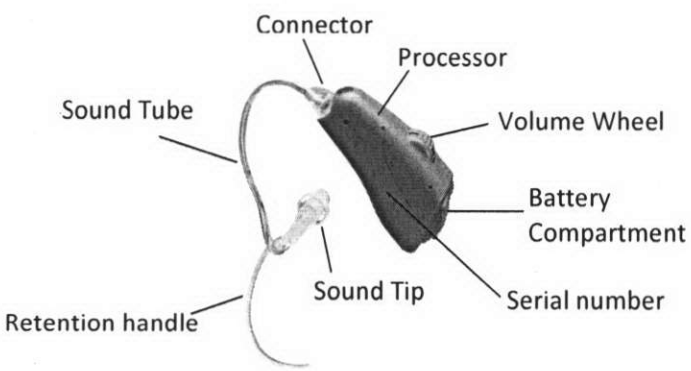
DATE OF SUBMISSIONS:	September 17, 2013
SUBMITTER:	Amplisound Hearing Products & Services 594 Putnam Road Danielson, CT 06239 Phone: (860)779-6500 Fax: (860)779-6501
CONTACT:	Ralph T. Campagna ralphc@amplisound.com
TRADE OR PROPRIETARY NAME:	Solace Sound Generators
MODEL:	Quell 908TD behind the ear
DEVICE COMMON NAMES:	Sound generators, tinnitus makers, noise generators
CLASSIFICATION NAME:	21 CFR 874.3400 (Tinnitus Masker Class II)
PRODUCT CODE:	KLW
PREDICATE DEVICES:	Resound TSG Module K073636 TTC's GHI-T & TN3-T Tinnitus Masker K982451

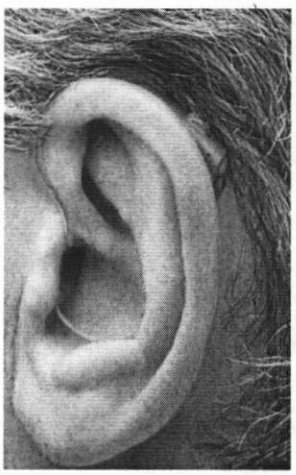
Device Description:

The Quell 908TD is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. These devices are programmable and offer the ability to adjust the frequency level of the masking sound to fit the individual user's needs. The programming can be done by hearing healthcare professionals using a standard HI-PRO box and Amplisound's Hearing Studio software. The Quell device resembles a miniature behind the ear (BTE) hearing aid. This style device sits on top of and just behind the pinna of the ear and has an acoustic soundtip connected to it. The soundtip is a removable and interchangeable tubing of different lengths, left and right, which carries the sound from the device into the ear. The soundtip connects to the device at one end and bends around the front of the pinna to the other end which is connected to a dome tip which fits inside the ear canal. Quell devices operate on a hearing aid battery and have an easily operated user volume control wheel. The wearer adjusts the sound to a desired loudness level by rolling the volume wheel with a fingertip.

Sound generators can be used for persons who suffer from tinnitus in conjunction with a sound therapy program such as Tinnitus Retraining Therapy (TRT). The sound therapy provides the tinnitus sufferer with an adjustable external sound source to mitigate the presence and annoyance of their personal internal noise.

Device Description – Quell model 908TD





Quell 908TD in place on the ear

The Quell 908TD sound generator consists of a miniature digital amplifier and speaker powered by a 1.4 volt battery packaged inside a small hearing aid shaped housing and which generates a digitally adjustable broad band white noise. White noise is defined as noise containing many frequencies at similar intensities. The bandwidth is adjustable from the broadest range of 750Hz to 8KHz, to the narrowest of 1250Hz to 3850Hz. The broad band noise is delivered through a small tubing connected to the housing which curves around the pinna and then is placed inside the ear canal. This small tubing is called a 'soundtip' which comes in left and right sides in short, medium and long lengths. There is a small plastic locking handle which helps retain the device in the ear, and a replaceable open dome tip in 6, 8, 10mm sizes to help the tip be comfortable and well seated in the ear canal.

Indications for Use:

Quell sound generators are designed for individuals who experience tinnitus. These devices generate a digitally controlled passive analog broad band noise from the circuit. The broad band noise is intended for use with tinnitus masking therapy. These devices are to be dispensed only by a doctor, licensed audiologist, or licensed hearing instrument specialist who are trained in the area of tinnitus treatment. BTE worn sound generators are one of several available sound stimuli means such as; computer generated audio, CD player, iPod, sound pillows, etc. Sound generators are dispensed to an adult population 18 years of age or above with specific instructions for their use.

Risks and Warnings for Safe Use:

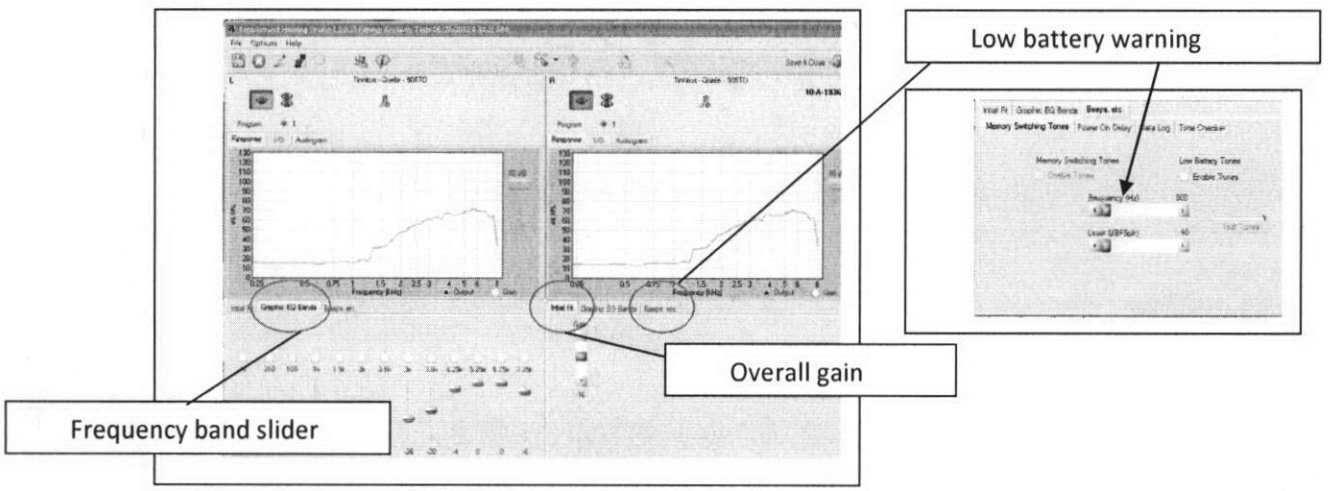
Because the maximum sound output level of the device is limited to safe levels determined by OSHA, there is no threat to the user with respect to damage to the ear caused by intensity of sound and noise exposure.

Rationale of the design:

Research on sound generators concludes that the primary characteristics of the design must include the following: a smooth broadband white noise response with minimal peaks, high frequency emphasis, a very gradual volume control taper with the ability to lower the sound to a zero dB noise floor, a reliable circuit that does not produce extraneous noises to the wearer, a comfortable housing design that is easy to wear and maintains a secure fit with an open canal.

Software/Programming

When needed, control of the sound emanating from the device is done with the use of programming software called "Hearing Studio". The Quell device is connected to a computer using a cable with flex connector and HiPro interface. The adjustments include tone of any combination of 12 frequency bands and an overall gain slider. There is also an adjustment of the low battery warning signal from 500, 1000, 1500, 2000Hz at a level of 60, 66, 72, 78dB. There is the option of turning this warning off.



Comparison Information to Predicate Devices

	Quell 908TD	Resound TSG Module	GHI –T & TN3 Masker
Characteristic	Sound Generator	Combination Device	Sound Generator
Models	BTE	BTE	BTE & ITE
Maximum output level	85 dB SPL	89 dB SPL	94 dB SPL
Battery drain	1.0 mA	1.2 mA	.4 - .5 mA
Peak output frequency	3KHz	3KHz	2700, 3600, 6000Hz
Energy source	Zinc-Air battery #10	Zinc-Air battery #312	Zinc-Air battery #10, 312,13
Intended use	Ear level worn sound generator or masking device for tinnitus.	Same	Same
Indications for use	Quell sound generators are designed for individuals who experience tinnitus. These devices generate a digitally controlled passive analog broad band white noise. The broad band noise is intended for use with tinnitus masking therapy. These devices are to be dispensed only by a doctor, licensed audiologist or licensed hearing instrument specialist who are trained in the area of tinnitus treatment.	This 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 and older.	These devices are intended for the adult population suffering from a chronic persistent ringing in the ears(tinnitus), who do not need or desire amplification. The products may be used for masking tinnitus as part of a tinnitus retraining therapy(TRT) protocol and should be utilized only in consultation with a licensed hearing healthcare professional who is trained in subsequent rehabilitation therapy, or a qualified audiologist.
Warnings	Maximum daily usage should be determined by the hearing healthcare professional.	same	same

The Amplisound Quell 908TD is comparable to two devices presently on the market - the ReSound TSG Module, which should be noted is a combination hearing aid/sound generator; and TTC's GHI-T and TN3 sound generator device. While it is not a hearing aid, Quell 908TD is similar to the predicate devices in that they are all ear level worn instruments that produce therapeutic sound for tinnitus sufferers. The difference between the Quell 908TD device and the predicate devices has primarily to do with the physical shape and style of the housing and the type of user volume control. The Quell 908TD has a scroll volume wheel, while the Resound has a toggle volume control and the GHI has a rotational volume control. All three devices are designed to minimize the amount of contact and occlusion of the ear canal , therefore keeping the canal open which is most desirable for sound therapy masking applications. By performing bench testing measurements with probe microphone on actual ears and 2cc ANSI tests in a test box, the sound output has been designed to mimic the predicate device's approved white noise characteristic which is a smooth response (void of any peaks) with less emphasis in the low frequencies and greater emphasis in the high frequencies. The Quell 908TD response is similar in frequency response to the predicate devices yet with lower maximum output to maintain safety and effectiveness. The Quell 908TD device is designed to be worn without any frequency adjustments for most wearers, however, the tone of the therapeutic sound is adjustable by the hearing care professional using the Hearing Studio software which employs band gain slider controls and overall gain control to adjust the frequency response of the sound as needed for individual patient needs. This software adjustment is similar to the Resound TSG module in that the low and high frequencies can be adjusted independently to 'tune' the masking sound if the user prefers a different tone. Output of the Quell 908TD device is limited within the fitting software to a maximum sound pressure level of 85 dB to meet the OSHA 29CFR 1910.95 standard. These settings include limits for the maximum user volume control wheel which is set by the hearing healthcare provider and cannot exceed 85dBspl.

Similar to the predicate devices, Quell 908TD sound generators are programmed, when needed, using the industry standard HiPro box and programming cables. The Quell 908TD device utilizes a standard micro behind the ear instrument housing and is powered by a size 10 zinc-air battery. Non clinical tests using probe microphone real-ear and 2cc test box measurements demonstrate that the Quell 908TD performs similarly to the comparative devices on the market designed for use with tinnitus treatment. Quell miniature BTE sound generator devices are similar in look, function and sound quality to the GHI and Resound ear level tinnitus devices already approved for the market and in use and by tinnitus sufferers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 25, 2014

Amplisound , Inc.
c/o Mr. Ralph Campagna
President
594 Putnam Road
Danielson, CT 06239

Re: K132965
Trade/Device Name: Solace Sound Generators
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: December 27, 2013
Received: December 30, 2013

Dear Mr. Campagna:

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,

Eric A. Mann -S

for 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

Amplisound, Inc.
Abbreviated 510(k) Submission
Solace Sound Generators

INDICATIONS FOR USE

510(k) Number: K132965

Device Name: Solace Sound Generators

Indications for Use:

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Prescription Use: _____ X _____ OR Over the Counter Use: _____

(Part 21 CFR 901 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDHR, Office of Device Evaluation (ODE)

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