MAR 1 8 2014

K133308

510(k) SUMMARY

Tinnitus SoundSupport

Submitter:	**Oticon A/S** Kongebakken 9 DK-2765 Smorum Denmark Phone: +45 3917 7100 Fax: +45 3927 7900
Contact Person:	Søren Juel Witt Oticon A/S Kongebakken 9 DK-2765 Smorum Denmark Mobile: +45 3030 2247
Date Prepared:	25. October 2013
Device Name:	Tinnitus SoundSupport
Device Class:	Class II
Classification Name:	Tinnitus Masker
Classification Regulation:	21 C.F.R. §874.3400
Product Code:	KLW
Predicate Devices:	K110932 Tinnitus Sound Generator, GnResound K123450 Tinnitus Balance Software, Phonak

Intended Use / Indications for Use

Tinnitus SoundSupport is a tool intended to generate sounds to provide temporary relief to patients suffering from tinnitus as part of a tinnitus management program.

The target population is the adult population (>18yrs).

Tinnitus SoundSupport is targeted for licensed hearing care professionals *(audiologists, hearing aid specialists, or otolaryngologists)* who are familiar with the evaluation and treatment of tinnitus and hearing losses. The fitting of

Tinnitus SoundSupport must be done by a hearing care professional participating in a tinnitus management program.

Technological Characteristics

. Oticon's Tinnitus SoundSupport consists of a software module added to the company's class II, 510(k)-exempt wireless air conduction hearing instruments legally marketed under 21 C.F.R. 874.3305.

Tinnitus SoundSupport is fitted to the patient by the Hearing Care Professional using Oticon fitting software.

Tinnitus SoundSupport provides the option of relief sounds based on white, pink or red noise. The relief sounds can be limited in frequency by high pass or low pass filters. Tinnitus SoundSupport also provides the option of amplitude modulation, a volume control and automatic level steering.

The design of Tinnitus SoundSupport is based on the controls of the Occupational Safety and Health Administration (OSHA). Compliance with OSHA controls is achieved through (1) output limitation and (2) professional labeling and (3) patient labeling.

Tinnitus SoundSupport must be used as part of a tinnitus management program.

Performance Data

Oticon's Tinnitus SoundSupport embedded software module and the Tinnitus tool in the fitting software has been verified and validated according to relevant standard for medical device software (Figure 7-1). In all instances, Oticon's Tinnitus SoundSupport functioned as intended and the performance observed was as expected.

Standards No.	Standards Title
IEC 62304	Medical device software - Software life-cycle processes

Figure 7-1.

The underlying class II, 510(k)-exempt wireless air conduction hearing instruments marketed legally by Oticon under 21 C.F.R. 874.3305 has been evaluated according to relevant standards. This includes evaluation in accordance with standards relating to EMC and electrical safety as well as biocompatibility (Figure 7-2). In all instances, the 510(k)-exempt hearing instruments functioned as intended and the performance was as expected.

Standards No.	Standards Title
ANSI C63.19-2007	American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids
IEC 60118-13	Electroacoustics – Hearing aids – Part 13: Electromagnetic compatibility (EMC)
IEC 60601-1-2:2007 + Corrigendum 5/2010	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
ETSI 301 489-3	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz
ETSI 300 330-2	Electromagnetic compatibility and Radio spectrum Matters (ERM);Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz Part 2: Harmonized EN under article 3.2 of the R&TTE Directive
FCC 47 CFR Part 15 §15.109, §15.209, §15.223	Title 47 of the Code of Federal Regulations; Chapter I Part 15 - Radio frequency devices - Radio frequency devices Operation in the band 1.705-10 MHZ.
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Figure 7-2.

Substantial equivalence

Oticon´s Tinnitus SoundSupport is as safe and effective as GnResound's Tinnitus Sound Generator (K110932) and Phonak's Tinnitus Balance Software (K123450). As shown in the table below, Oticon´s Tinnitus SoundSupport, GnResound's Tinnitus Sound Generator (K110932) and Phonak's Tinnitus Balance Software (K123450) have the same intended use and similar indications, technological characteristics and principles of operation. Minor technological differences do not present any new issues of safety or effectiveness. Thus, Oticon´s Tinnitus SoundSupport is substantially equivalent to GnResound's Tinnitus Sound Generator (K110932) and Phonak's Tinnitus Balance Software (K123450).

Comparison table

Oticon A/S.

Tinnitus SoundSupport
SUBSTANTIAL EQUIVALENCE CHART

Device	*New*	*Predicate*	*Predicate*
Manufacturer	Oticon	GN Resound	Phonak
Name	Tinnitus SoundSupport	Tinnitus Sound Generator	Tinnitus Balance software
510(k) #		K110932	K123450
Indications for use	Tinnitus SoundSupport is a tool intended to generate sounds to provide temporary relief to patients suffering from tinnitus as part of a tinnitus management program. The target population is the adult population (>18yrs). Tinnitus SoundSupport is targeted for licensed hearing care professionals (audiologists, hearing aid specialists, or otolaryngologists) who are familiar with the evaluation and treatment of tinnitus and hearing losses. The fitting of Tinnitus SoundSupport must be done by a hearing care professional participating in a tinnitus management program.	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 a hearing professional participating in a Tinnitus Management Program.	The target group for the Phonak Tinnitus Balance software feature are adult 18 years of age or older with tinnitus who also desire amplification. The Tinnitus Balance software feature and accompanying hearing aid amplification is fit by a licensed hearing healthcare professional (audiologist, hearing aid specialist, otolaryngologist) familiar with the diagnosis and management of tinnitus. Phonak hearing aids provide amplification to address sensorineural, conductive, or mixed hearing losses. Depending on the specific model, Phonak hearing aids cover fitting range from mild to profound hearing losses. Before being fit with Tinnitus Balance, individuals presenting with tinnitus should be assessed by a licensed ear physician to confirm

			the source of their tinnitus is not due to any of the following medical conditions: • Visible congenital or traumatic deformity of the ear • Any active drainage from the ear within the previous 90 days • Sudden hearing loss within the previous 90 days • Acute or chronic dizziness • Unilateral hearing loss of sudden or recent onset within the previous 90 days • Pain or discomfort in the ear
User population	Adult population (>18yrs)	Primarily adult population (>18yrs), can be used for patients >5yrs	Adult population (>18yrs)
Schedule of use	All day	All day in all environments	Throughout the day
Mechanism	Volume is set by HCP and can be adjusted by patient, when in use. Default level fixed. Amplitude modulation and steady noise. Sound colors: White, pink and red. Noise can be configured from broad band to narrow band customized to the patient.	Volume is set by HCP and can be adjusted by patient, when in use. Default level fixed. Amplitude modulation and steady noise. Sound color: White. Noise can be configured from broad band to narrow band customized to the patient.	Volume is set by HCP and can be adjusted by patient, when in use. Default level based on users hearing level. Steady noise. Sound colors: White and pink. Noise can be configured from broad band to narrow band customized to the patient.
Technological Characteristics	Software module embedded into a digital hearing instrument platform.	Software module embedded into a digital hearing instrument platform.	Software module embedded in a digital hearing aid platform.

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 18, 2014

Oticon A/s
c/o Mr. Søren Juel Witt
Senior Regulatory Affairs Officer
Kongebakken 9
DK-2765 Smørum
Denmark

Re: K133308
Trade/Device Name: Tinnitus Soundsupport
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: February 10, 2014
Received: February 14, 2014

Dear Mr. Witt:

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

Indications for Use Statement

510(k) Number (if known): K133308

Device Name: Tinnitus SoundSupport™

Indications for Use

Tinnitus SoundSupport is a tool intended to generate sounds to provide temporary relief to patients suffering from tinnitus as part of a tinnitus management program.

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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)

Cherish R. Giusto -S