K123450

## 5. 510(k) Summary

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| **Submitter:** | Phonak, LLC | |
| | 4520 Weaver Parkway | |
| | Warrenville, IL 60555 | |
| **Contact Person:** | Laura Ellman | |
| | (630) 821-5000 | |
| **Date Prepared:** | October 1st 2012, revised January 21st, 2013 | |
| **Device Name:** | Phonak Tinnitus Balance software feature | |
| **Classification Name:** | Tinnitus Masker | |
| **Product Code:** | KLW | |
| **Predicate Devices:** | K110932 | Tinnitus Sound Generator Module, GN ReSound A/S |
| | K110973 | IE-Zen (in CLEAR series hearing aid), Widex USA |
| | K003558 | TCI-Combi, Siemens Hearing Instruments |

**Description of Device**

The Tinnitus Balance software feature is a broadband noise generator embedded in the firmware of selected Phonak hearing aids. It provides a means of sound enrichment that can be used as part of a tinnitus management program to provide relief from tinnitus. By combining a broadband noise generator and hearing aid, the patient is able to wear a single device throughout the day for both tinnitus relief and amplification. The Tinnitus Balance software feature is enabled and fit by a licensed hearing healthcare professional together with the hearing aid's amplification to meet the individual needs of the patient.

**Intended Use**

The Phonak Tinnitus Balance software feature is intended for use by people with tinnitus who also desire amplification. It provides supplementary noise stimulation which can help defocus the user's attention from their tinnitus. The initial spectral characteristics of Tinnitus Balance can either be determined by the patient's audiogram as measured by the hearing healthcare professional, or broadband white noise. The spectral characteristics can be adjusted by the HCP to fit the needs of the patient as part of their customized tinnitus management program.

**Technological comparison to predicate devices**

The Tinnitus Balance software feature shares the same basic technology used by the three predicate devices. It shares the following technological principles with the GN ReSound Tinnitus Sound Generator Module predicate device (K110932):

- Embeds a broadband noise generator software feature in a digital hearing aid platform
- Feature can be made available in multiple hearing programs during fitting and uses a similar approach for volume adjustment by the patient

Principles that differ from Tinnitus Sound Generator Module are:

- Maintains the noise at a constant output level for the patient as specified during fitting and does not vary the amplitude or frequency
- Limits the maximum output of the generated noise to 85 dB(A) SPL independent of maximum hearing aid output

The Tinnitus Balance software feature shares the following technological principles with the IE-Zen (in CLEAR series hearing aid) predicate device (K110973):

- Embeds a noise generator software feature in a digital hearing aid platform comprising wireless hearing aid models
- Feature can be made available in multiple hearing programs during fitting and uses a similar approach for volume adjustment by the patient

Principles that differ from IE-Zen are:

- Provides only a broadband noise generator and no musical tones
- Limits the maximum output of the generated noise to 85 dB(A) SPL independent of maximum hearing aid output

The Tinnitus Balance software feature shares the following technological principles with the TCI-Combi predicate device (K003558):

- Embeds a broadband noise generator software feature in a digital hearing aid platform comprising non-wireless hearing aid models
- Feature can be made available in multiple hearing programs during fitting and uses a similar approach for volume adjustment by the patient

Principles that differ from TCI-Combi are:

- Limits the maximum output of the generated noise to 85 dB(A) SPL independent of maximum hearing aid output

The Tinnitus Balance software feature does not introduce any new types of generated noise or levels that may introduce safety or effectiveness concerns.

## Performance Testing

Phonak has conducted a risk analysis and performed the necessary verification and validation activities to demonstrate the design outputs meet the design inputs of the Tinnitus Balance software feature.

Phonak has conducted a review of published scientific literature to confirm the safety and effectiveness of the Tinnitus Balance software feature in line with the stated intended use.

## Conclusion

Performance testing of the Tinnitus Balance software feature indicates it is safe, effective and performs as well as the predicate devices.

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

February 11, 2013

Phonak, LLC
% Ms. Laura Ellman
Quality Manager
4520 Weaver Parkway
Warrenville, IL 60555

Re: K123450
Trade/Device Name: Phonak Tinnitus Balance software feature
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: October 30, 2012
Received: November 13, 2012

Dear Ms. Ellman:

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 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

510(k) Number (if known): K123450

Device Name: Phonak Tinnitus Balance software feature

Indications For Use:

The target group for the Phonak Tinnitus Balance software feature are adults 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 ranges 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

Prescription Use: X AND/OR Over-The-Counter Use : ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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