July 13, 2018

GN Hearing A/S
Lars Hagander
Vice President, Corporate Quality
Lautrupbjerg 7
Ballerup, 2750 Dk

Re: K181586
Trade/Device Name: Tinnitus Sound Generator Module
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: June 12, 2018
Received: June 15, 2018

Dear Lars 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. 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Srinivas Nandkumar -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181586

Device Name
Tinnitus Sound Generator Module

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## II. 510(K) SUMMARY

### 510(k) SUMMARY

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|---|---|
| **Submission Type:** | **Special 510(k)** |
| **Submitter:** | **GN Hearing A/S**<br>Lars Hagander<br>Lautrupbjerg 7<br>DK-2750 Ballerup<br>Denmark<br>Phone: +45 45 75 11 11<br>Registration number: 3005650109 |
| **Date Prepared:** | **June 12, 2018** |
| **Device Name:** | **Tinnitus Sound Generator Module** |
| **Device Class:** | **Class II** |
| **Classification Name:** | **21 CFR 874.3400 *Tinnitus masker*** |
| **Classification Panel:** | **Ophthalmic and Ear, Nose, and Throat Division** |
| **Product Code:** | **KLW** |
| **Predicate Device:** | **K150171** |

**Device Description**

The Tinnitus Sound Generator provides a means for healthcare professionals to create a hearing instrument solution that provides relief for Tinnitus patients. This software solution is embedded into a digital hearing instrument platform, so that the end-user can wear this device in all environments. The fitting of the digital device, which contains the Tinnitus Sound Generator module, is performed by a healthcare professional, in order to meet the exact needs of the Tinnitus patient.

A mobile medical application (app) is available as an optional device to use with the Tinnitus Sound Generator. The mobile medical app allows the user to adjust the hearing aid within the limits set by the healthcare professional during fitting of the hearing aid. The app is known as the TSG Tinnitus Manager app.

**Predicate Device**

K150171 Tinnitus Sound Generator Module by GN ReSound A/S

**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.

**Indication for Use statement**

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.

**Technological Characteristics Comparison**

There are seven modifications (Microphone always enabled, Shared volume control for TSG noise level and microphone inputs, Shared synchronization control, Removed smooth transition when switching towards one of the AM attenuation modes, White noise bandwidth extended from 7 kHz to 9.5 kHz, Low pass filter extended to 8kHz, and New coding language on C5 platform).

The revisions to the Tinnitus Sound Generator module are technological software advancements that improve the functionality of the device, whilst having minimal risk to the patient and are minor modifications in relation to the predicate device that do not change the operating principle of the TSG module.

**Performance Data**

GN Hearing has conducted a risk analysis and has performed the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements.
Successful Verification is done one-to-one for all product requirements, with proper traceability. The verification shows substantial equivalence to the predicate device, also verified in house. The verification also includes a successful System Verification including all the devices interacting with the modified device.
Successful Validation is done with focus on evaluating stability, clinical performance and the objective and subjective benefit of the modified device. The Validation is done as part of a System Validation, including all the devices interacting with the modified device. The Validation show substantial equivalence to the predicate device, also validated in house.

**Other – Pediatric 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.

**Conclusions**

Modifications to the device do not raise new or different questions of safety or effectiveness for the device's intended use. The results of risk analysis and design verification and validation activities provide evidence that the device is as safe and effective as its predicate. This therefore demonstrates that the TSG module is substantially equivalent to its predicate device.