February 20, 2020

GN Hearing A/S
Lars Hagander
Vice President Corporate Quality
Lautrupbjerg 7
DK 2750 Ballerup
Denmark

Re: K193303
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: January 17, 2020
Received: January 21, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K193303

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 temporarily 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 initial fitting of the Tinnitus Sound Generator Module must be done during an in-office visit by a hearing professional participating in a Tinnitus Management Program. If deemed feasible by the hearing professional, subsequent fittings of the Tinnitus Sound Generator Module may be performed remotely and in real time while having live communication via live audio, video and chat on the user's dedicated app.

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.

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510(k) SUMMARY

I) SUBMITTER

Submission Type: **Special 510(k)**

Submitter: **GN Hearing A/S**
Lautrupbjerg 7
DK-2750 Ballerup Denmark
Phone: +45 45 75 11 11

Contact Person: **Lars Hagander**

Date Prepared: **February 13, 2020**

II) DEVICE

Trade or Proprietary Name: **Tinnitus Sound Generator Module**

Common or Usual Name: **Tinnitus Masker**

Classification Name: **21 CFR 874.3400** ***Tinnitus masker***

Regulatory Class: **Class II**

Classification Panel: **Ear, Nose, and Throat**

Product Code: **KLW**

III) PREDICATE DEVICE

Predicate Device: **K180495**

IV) DEVICE DESCRIPTION

The Tinnitus Sound Generator (TSG) Module is software that provides a means for healthcare professionals to create a hearing instrument solution that provides temporary relief for Tinnitus patients. This software solution is embedded into a digital hearing instrument platform, so that the end-user (EU) can wear this device in all environments. The fitting of the digital device, which contains the TSG 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 TSG. 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 and is part of the Smart3D app. The Smart3D app also enables a

Health Care Professional (HCP) to remotely adjust the TSG settings using a Remote Fine Tuning Feature (RFT). The Support for the RFT feature for the TSG Module can be enabled by the doctor, audiologist or other hearing healthcare professional, at the time of first fitting. Afterwards, the doctor, audiologist or other hearing healthcare professional is able to remotely make adjustments to TSG Module settings.
RFT is only enabled when the doctor, audiologist or other hearing healthcare professional finds it feasible, based on an initial in-office assessment of the user and communication with the user, and the parent or legal guardian in cases where the user is a minor. Subsequent to the in-office assessment, the user, or the parent or legal guardian in cases where the user is a minor, is required to accept to receive the adjustments via the TSG portion of the Smart3D app, called the Tinnitus Manager.

Compared to the Remote Fine Tuning, available in the predicate device, the subject TSG Module additionally supports Remote Fitting, being used for real time, online adjustments, with live communication with the end user. Support for Remote Fitting is a process where the end user (EU) has a scheduled appointment with the hearing Health Care Professional (HCP) while the EU is at a remote location, like at home. HCP and EU meet via an HCP initiated live audio, live video and chat on the user's Smart3D app, and adjustments can be made to the Hearing Aids per agreement and prescription of the HCP. During this process, the HCP can make multiple adjustments in real time to the Hearing Aids, including TSG, while having live communication with the EU as if they were in the same room. The session is similar to an adjustment session done at the HCP office, but with the EU at a remote location. When the final settings are decided, a fitting data package is generated by the HCP, and the Hearing Aids are updated remotely while having the live session with the EU. Subsequent to the in-office assessment, the user, or the parent or legal guardian in cases where the user is a minor, is required to accept the adjustments. The Remote Fitting is only made available and technically working for follow-up sessions when found feasible by the HCP, and not available for the initial first-time fitting of the Hearing Aids, that has to take place at the HCP office.

V) INDICATIONS FOR USE / INTENDED USE

The Tinnitus Sound Generator Module is a tool to generate sounds to be used in a Tinnitus Management Program to temporarily 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 initial fitting of the Tinnitus Sound Generator module must be done during an in-office visit by a hearing professional participating in a Tinnitus Management Program. If deemed feasible by the hearing professional, subsequent fittings of the Tinnitus Sound Generator Module may be performed remotely and in real time while having live communication via live audio, video and chat on the user's dedicated app.

The Indications for Use are not identical to those of the predicate device. However, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use, i.e., to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus.

VI) COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

All of the new device's technological characteristics are identical to those of the predicate device except for one modification: the addition of Support for Remote Fitting, which is technically supported by the TSG software in the predicate device. This means that the TSG software is unchanged, but now claims support for the added Remote Fitting feature. The Remote Fitting feature is implemented in the Fitting Software used by the HCP, at the HCP office, and the App used by the EU.
The unchanged TSG software supports the Remote Fitting using already implemented services.

The Remote Fitting is only available and technically working for follow-up adjustment sessions, and not available for the initial first-time fitting of the Hearing Aids, that still has to take place at the HCP office. The Remote Fitting is only used when found feasible by the HCP, based on a clinical judgement. The EU, or the parent or legal guardian in cases where the user is a minor, is required to accept the changes.

This modification to the technological characteristics of the subject device, has minimal risk to the patient and based on the risk analysis, all risks are mitigated to an acceptable level. The minor modification in relation to the predicate device does not change the basic operating principle of the TSG module.

VII) 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 in relation to supporting the Remote Fitting feature. Changes are verified and validated using the same well-established software design model, with same verification and validation method as used in the previously cleared 510(k). The acceptance criteria were not altered, and no additional types of evaluation was needed.

The TSG Module is verified in an integrated system verification test. The integrated system consists of:

- Different Hearing Instrument hardware with embedded software, including the TSG Module.
- App (iOS & Android)
- Fitting Software (FSW)

The system verification includes system end-to-end testing and interoperability performance testing. The result of the system verification show that tests has passed with no defects critical for function, form, intended use, or pose any user risks.

The successful validation activities conducted for the subject device are based on experience with similar validation method and activities for the predicate device. The successful validation activities related to the Support for Remote Fitting feature were conducted to show that human factors and usability are safe and effective as the predicate device.

VIII) CONCLUSIONS

The modification to the technological characteristics of the new device, i.e., support for the added Remote Fitting feature, does not raise new or different questions of safety or effectiveness as compared to the predicate device. The results of risk analysis and design verification and validation activities provide evidence that the new device is as safe and effective as its predicate and therefore, demonstrate that the TSG Module is substantially equivalent to the predicate device.