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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

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
Continued on separate page if needed

Type of use (select one or both, as applicable):

Device Name

Indications for Use

Title: Timeless SonoCeptor Module

Device Name: K184049S

510(k) Number (if known): 0000-000000

Expiry Date: 06/06/2020

Form Approved: OMB No. 0910-0120

Food and Drug Administration

Department of Health and Human Services

Healthcare professional participating in a Tobacco Management Program.

Timeless, as well as conventional tobacco disorders, the timing of the Timeless SonoCeptor module must be done by a

Timeless SonoCeptor module is intended for healthcare professionals, which are health professionals. The

Tobacco SonoCeptor Module is used to treat tobacco use disorders and is not intended for use in a Tobacco Management Program.

Indications for Use (casestudy)

The Tobacco SonoCeptor Module is intended for healthcare professionals. A Tobacco Management Program is

In cases of age, this product may also be used with children 7 years of age or older.

Examples of tobacco use disorders include smoking, the withdrawal of nicotine from the body, and the prevention of tobacco use in children 16 years of age or older.

The Tobacco SonoCeptor Module is intended for healthcare professionals. A Tobacco Management Program is

In cases of age, this product may also be used with children 7 years of age or older.

Examples of tobacco use disorders include smoking, the withdrawal of nicotine from the body, and the prevention of tobacco use in children 16 years of age or older.
510(k) SUMMARY

Submission Type: Traditional 510(k)

Submitter: GN Hearing A/S
Lars Hagander
Lautrupbjerg 7
DK-2750 Ballerup
Denmark
Phone: +45 45 75 11 11
Registration number: 3005650109

Date Prepared: November 28, 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: Tinnitus Sound Generator Module, K181586

Reference Device: LiNX3D model hearing aid, Class II Exempt from 510(k) procedures

Device Description
The Tinnitus Sound Generator (TSG) Module 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 subject TSG Module has a new feature, i.e., Remote Fine-tuning (RFT) communication software (PC Interface software) that communicates with a healthcare professional’s Fitting Software (FSW) via the user’s Smart3D app and is part of the general software on the digital signal processor in GN’s legally marketed, class II, 510(k) exempt Hearing Aids (Reference Device). The RFT communication software in the Reference device enables the healthcare professional to remotely adjust the Hearing Aid settings for these legally marketed, class II, 510(k) exempt Hearing Aids, including Hearing Aids that are compatible with the predicate TSG Module and the new TSG Module.

Similarly, the new TSG Module has a PC Interface Software modification that supports fine tuning of TSG Module settings from a remote location. The new TSG Module’s PC Interface Software modification opens a bridge between the general RFT function on the Hearing Aid’s digital signal processor and the TSG feature settings, that are also available for adjustments via the user’s Smart3D app. Therefore, the RFT communication software part of the general software on the Hearing Aids containing the new TSG Module is also part of new TSG Module device.

The Health Care Professional (HCP) can make all of the same changes (Volume/loudness, Pitch/frequency, Nature sounds, and Amplitude modulation) that the user can make. Additionally, the HCP can turn the TSG/tinnitus masker on or off and can set and adjust the Volume Control range and environmental steering sounds. The TSG Volume Control range feature is available only to the HCP. This feature allows the HCP to set a limit on the TSG volume range an EU can adjust. This feature is specifically designed for the safety of the EU, ensuring that an EU cannot increase the TSG volume above a level determined appropriate by the HCP. The system can in no case exceed 100dB SPL for TSG. The TSG Volume Control range has a range of +12dB to -6dB from the TSG fitting by the HCP and can be found in the FSW under the Fitting / Manual Controls / Volume Control Range. For example, if the HCP sets the TSG Volume Control range to +6dB to -6dB, this means an EU cannot set the TSG volume more than 6dB above or below the initial fitting.

**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.

**Indications for Use statement**

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 fitting of the Tinnitus Sound Generator module must be done by a hearing professional participating in a Tinnitus Management Program.

The Indications for Use Statement for the new device is not identical to that of the predicate device in that the word “temporarily” is added to clarify relief from Tinnitus provided by the new TSG Module is...
This minor modification does not impact safety or effectiveness and both the new and predicate devices have the same intended use.

**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 RFT, which is a PC Interface Software modification that supports fine tuning from a remote location of each of the TSG Module’s settings that can be adjusted by the EU (or parent or guardian in the case of a minor) and/or the HCP using the FSW in the clinic.

The subject TSG Module’s new RFT communication software communicates with a healthcare professional’s FSW via the user’s Smart3D app and is part of the general software on the digital signal processor in GN’s legally marketed, class II, 510(k) exempt Hearing Aids (Reference Device). The RFT communication software in the Reference device enables the healthcare professional to remotely adjust the Hearing Aid settings for these legally marketed, class II, 510(k) exempt Hearing Aids, including Hearing Aids that are compatible with the predicate and new TSG modules.

Similarly, the new TSG Module’s PC Interface Software modification supports fine tuning of TSG Module’s settings from a remote location. The predicate TSG module device does not contain a RFT feature to adjust its parameters from a remote location.

The TSG Module’s PC Interface Software modification opens a bridge between the general RFT function on the Hearing Aid’s digital signal processor and the TSG Module’s parameter settings that are also available for adjustments via the EU’s Smart3D app. Therefore, the RFT communication software part of the general software on the Hearing Aids containing the new TSG Module’s is also part of new TSG Module.

The new RFT feature is only enabled by the healthcare professional if the healthcare professional finds it feasible, based on an initial in-office assessment of the EU. The app requires the EU, or the parent or legal guardian in cases where the user is a minor, to answer an inventory of questions to better understand the EU’s need for the new RFT request, and the request is sent to the healthcare professional. Based on the request, and a clinical judgement, the healthcare professional will send the fine-tuned settings to the EU. If the healthcare professional feels the request is against their best clinical judgement, or ‘out of the ordinary’, the healthcare professional should first request a face-to-face/live follow-up visit (e.g., phone call, email, clinical visit) prior to making any changes via RFT. The EU, or the parent or legal guardian in cases where the user is a minor, is required to accept the changes.

This one modification to the technological characteristics of the new device, i.e., the addition of Support for RFT, which is a PC Interface Software modification, has minimal risk to the patient and based on the risk analysis, all risks have been mitigated to an acceptable level. The combined minor differences between the Indications for Use (the addition of the word “temporarily”) and the single technological change (the addition of Support for RFT for the adjustable parameters of the TSG Module) 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.

Besides the detailed verification of all requirements, 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 test 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 activities for the predicate device and reference device. The successful validation activities related to the RFT feature were conducted to show that human factors and usability are safe and effective.
The reference device, LiNX3D hearing aid, meets the special controls identified in 21 CFR 874.3305:

<table>
<thead>
<tr>
<th>21 CFR 874.3305 Special controls</th>
<th>Reference device LiNX3D</th>
<th>Remote Fine Tuning part of LiNX3D</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Appropriate analysis/testing should validate electromagnetic compatibility (EMC) and safety of exposure to non-ionizing radiation</td>
<td>EMC testing was done in accordance to the appropriate standards IEC 60601-1-2 and IEC 60118-13. EMF assessment was done in accordance to IEC 62311 and IEC 62479. The tests and the assessment were performed by the accredited test house: DEKRA Testing and Certification, S.A.U. Parque Tecnológico de Andalucía, c/ Severo Ochoa nº 2, 29590 Campanillas, Málaga, Spain. Test reports demonstrate compliance to the FDA medical device recognized standards, and the regulatory radio requirements in relation to the US Federal Communications Commission (FCC). The testing and the assessment demonstrate that the implemented wireless technology is safe.</td>
<td>The RFT feature does not operate using a different technology than the other wireless hearing aid features.</td>
</tr>
<tr>
<td>(2) Design, description, and performance data should validate wireless technology functions</td>
<td>The design controls activities for the LiNX3D hearing aid are identical to the activities described in Annex IX of the K180495 submission. The GN Hearing New Product Development process #0216640 were followed. The wireless technology was developed and documented as part of this process and performance data in the form of verification of all wireless technology requirements</td>
<td>The RFT feature does not operate using a different wireless technology than the other wireless hearing aid features. The features using the wireless technology in relation to RFT were verified and validated to be safe and effective as part of the design process.</td>
</tr>
</tbody>
</table>
(3) Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation

Risk controls related to wireless technology, identified as part of the Risk Management, include labeling requirements with appropriate instructions, warnings, and information related to EMC and wireless technology and human exposure to non-ionizing radiation. The user guide informs the user about the device containing a RF transmitter operating wireless, and the precautions related to that, like coexistence with other devices, flight mode, etc.

RFT uses the same wireless technology for communication as the standard hearing aid functionalities. No additional labeling required.

The system verification outcome, together with the TSG Module verification and validation outcome, supports substantial equivalence of the subject device compared to the Predicate Device, verified and validated under similar conditions at GN Hearing.

The system verification outcome, together with the TSG Module verification and validation outcome, also supports substantial equivalence of the RFT Feature in the subject device compared to the predicate device, showing that RFT is safe and effective.

**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.

The volume control is a feature in the TSG module used for adjusting the sound generator output level. To prevent unintended usage by pediatric or physically or mentally challenged users, the volume control must be configured to only provide a decrease of the sound generator output level.

Adjustment of the tinnitus sound generator settings, using a smartphone app, should only be performed by the parent or legal guardian in cases where the user is a minor. Use of the ReSound Assist for remote settings of the tinnitus sound generator, should only be performed by the parent or legal guardian in cases where the user is minor.

The RFT feature will only be used under clinical supervision from a Hearing Care Professional. Initial fitting must be done face-to-face in the office of the hearing care professional and RFT should only be used for follow-up adjustments.
The user is informed to discontinue use of the sound generator and consult promptly with a licensed physician if they experience one of the following conditions:

a. Visible congenital or traumatic deformity of the ear.
b. History of active drainage from the ear within the previous 90 days.
c. History of sudden or rapidly progressive hearing loss within the previous 90 days.
d. Acute or chronic dizziness.
e. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
f. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
g. Pain or discomfort in the ear.

The user is also informed to discontinue use of the sound generator and consult promptly with the hearing care professional if they experience changes in the tinnitus perception, discomfort or interrupted speech perception, while using the tinnitus sound generator.

**Conclusions**
The single minor modification to the Indications for Use statement and the one minor modification to the technological characteristics of the new device do 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.