February 1, 2023

Goldenear Company, Inc.
Daehee Lee
CEO
24207 Via Perla
Santa Clarita, California 91354

Re: K221168
Trade/Device Name: Tinnitogram Signal Generator
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: January 5, 2023
Received: January 5, 2023

Dear Daehee Lee:

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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221168

Device Name
TINNITOGRAM™ SIGNAL GENERATOR

Indications for Use *(Describe)*
Tinnitogram™ Signal Generator is a sound generating software used in a Tinnitus Management Program designed to provide temporary relief for people experiencing tinnitus symptoms. It is intended primarily for adults over 18 years of ages, but may also be used for children 5 years of age or older.
Tinnitogram™ Signal Generator is for use by hearing healthcare professionals who are familiar with the evaluation and treatment of tinnitus and hearing losses. A hearing healthcare professional should recommend that patient listen to the Tinnitogram™ Signal Generator signal for 30 minutes twice a day at the barely audible level (minimally detectable level).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary
(TINNITOGRAM™ SIGNAL GENERATOR)

Submitter: GOLDENEAR COMPANY, INC.
24207 Via Perla, Santa Clarita, CA 91354
Phone: (661) 207-1307

Contact Person: Daehee Lee
E-mail: day@Goldenearclub.com

Submission Number: K221168

Date Prepared: Feb 1, 2023

Device Name: TINNITOGRAM™ SIGNAL GENERATOR

Software Version: V1.0

Device Class: Class II

Classification Name: Tinnitus Masker

Classification Regulation: 21 C.F.R. 874.3400

Product Code: KLW

Predicate Device: K151719 REVE134, KW Ear Lab

Prior Related Submission: No prior submissions for the subject device

Intended Use / Indication for Use:

Tinnitogram™ Signal Generator is a sound generating software used in a Tinnitus Management Program designed to provide temporary relief for people experiencing tinnitus symptoms. It is intended primarily for adults over 18 years of ages, but may also be used for children 5 years of age or older.
Tinnitogram™ Signal Generator is for use by hearing healthcare professionals who are familiar with the evaluation and treatment of tinnitus and hearing losses. A hearing healthcare professional should recommend that patient listen to the Tinnitogram™ Signal Generator signal for 30 minutes twice a day at the barely audible level (minimally detectable level).

Technological Characteristics:

GOLDENEAR COMPANY's TINNITOGRAM™ SIGNAL GENERATOR is a software as a medical device recommended to use a PC (desktop or laptop computer). TINNITOGRAM™ SIGNAL GENERATOR is fitted to the patient by the healthcare professional. The software enables qualified professional to create customized sounds with specific frequency range for sound therapy/masking.

Device type is Stand-alone software as a medical device.

The tinnitus masking signal is generated through a pre-process of securing the patient's customized signal. The test to find tinnitus frequencies, the pre-process, is performed automatically and this masking signal is generated at patient's barely audible level.
The test sound specifications to find tinnitus frequencies of TINNITOGRAM™ SIGNAL GENERATOR are as follows:
· Maximum output is 1 kHz, 104 dB SPL (based on ISO 226:2003);
· Initial output is 54 dBr;
· Measurement frequency range is 262~11840 Hz (audible frequency range) and it consists of 67 bands;
· Pulse repetition count of pulsatile pure tone is 10 times/sec; and
· Beep type is Pulse Tone with 10 times/sec, 50 ms rise-fall time.

The sounds that can be generated with the TINNITOGRAM™ SIGNAL GENERATOR software are detailed as follows:
· The bandwidth of modulated white noise is 233~12912 Hz.
· The frequency range of modulated narrow band noises / tones has a frequency range of approximately 1/3 octave, and it depends on patient's hearing threshold.

Performance Data:

GOLDENEAR COMPANY's TINNITOGRAM™ SIGNAL GENERATOR software as a medical device has been verified and validated according to relevant standards for medical device software and risk management procedure below. In all verification and validation process, GOLDENEAR COMPANY's TINNITOGRAM™ SIGNAL GENERATOR functioned properly as intended and the performance observed was as expected.

Standard No.	Standard Title
IEC62304:2006/ Amd 1:2015	Medical device software – Software life-cycle processes
ISO14971:2019	Medical devices – Application of risk management to medical devices

Comparison Table:

GOLDENEAR COMPANY Inc. TINNITOGRAM™ SIGNAL GENERATOR

Substantial Equivalence Chart

Device	Subject	Predicate	Discussion
Manufacturer	GOLDENEAR COMPANY	KW Ear Lab	
Name	Tinnitogram™ Signal Generator	REVE134	
510(K) No.	K221168	K151719	
Indication for Use	Tinnitogram™ Signal Generator is a sound generating software used in a Tinnitus Management Program designed to provide temporary relief for people experiencing tinnitus symptoms. It is intended primarily for adults over 18 years of ages, but may also be used for children 5 years of age or older. Tinnitogram™ Signal Generator is for use by hearing healthcare professionals who are familiar with the evaluation and treatment of tinnitus and hearing losses. A hearing healthcare professional should recommend that patient listen to the Tinnitogram™ Signal Generator signal for 30 minutes twice a day at the barely audible level (minimally detectable level).	REVE134 is a sound generating software used in a Tinnitus Management Program designed to provide temporary relief for people experiencing tinnitus symptoms. It is intended primarily for adults over 18 years of ages, but may also be used for children 5 years of age or older. REVE134 is for use by hearing healthcare professionals who are familiar with the evaluation and treatment of tinnitus and hearing losses. A hearing healthcare professional should recommend that patient listen to the REVE134 signal for 30 minutes twice a day at the barely audible level (minimally detectable level).	Same
User Population	Primarily adult population (>18yrs), can be used for patients >5yrs	Primarily adult population (>18yrs), can be used for patients >5yrs	Same
Schedule of Use	All day	All day	Same
Mechanism	Volume is set by HCP and can be adjusted by patients, when in use. Default level fixed. Amplitude modulation noise and frequency modulation pure tone.	Volume is set by HCP and can be adjusted by patients, when in use. Default level fixed. Amplitude modulation noise and frequency modulation pure tone.	Same
Type of Use	Prescription Use	Prescription Use	Same
Recommended Device to Use	a software as a medical device recommended to use a PC (desktop or laptop computer)	software installed in PC (desktop or laptop computer)	Same

Device Type	Stand-alone software	Software module embedded into a digital hearing instrument platform	Different
How to Perform Test	The test to find tinnitus frequencies is performed automatically and this masking signal is generated at patient′s barely audible level.	A hearing healthcare professional needs to adjust default value into patient's barely audible level.	Different
Test Sound Specifications	· Maximum output is 1 kHz, 104 dB SPL (based on ISO 226:2003). · Initial output is 54 dBr. · Measurement frequency range is 262~11840 Hz (audible frequency range) and it consists of 67 bands. · Pulse repetition count of pulsatile pure tone is 10 times/sec. · Beep type is Pulse Tone with 10 times/sec, 50 ms rise-fall time.	· Maximum output is 1 kHz, 84 dB SPL. · Initial output is 54 dBr. · Measurement frequency range is 233~12912 Hz. · Tone type is modulated narrow band tones.	Different
Generated Sound	Customized sounds with specific frequency range for sound therapy / masking	Customized sounds with specific frequency range for sound therapy / masking	Same
Generated Sound Specifications	· The bandwidth of modulated white noise is 233~12912 Hz. · The frequency range of modulated narrow band noises / tones has a frequency range of approximately 1/3 octave, and it depends on patient's hearing threshold.	REVE134 software can generate either modulated white noise (233~12912 Hz) or modulated narrow band noises or tones with specific frequency range. One narrow band noise has a frequency range of approximately 1/3 octave.	Same

Substantial Equivalence:

GOLDENEAR COMPANY's TINNITOGRAM™ SIGNAL GENERATOR is as safe and effective as KW Ear Lab's REVE134 (K151719). As shown in the table above, the subject device has the same indications for use, user population, and mechanism as its predicate device. Test sound specifications, device type, and how to perform test are different as those of the predicate device. However, these differences in test sound specifications (e.g., maximum output level) do not raise different questions of safety and effectiveness. Bench performance testing of the subject device has been conducted to demonstrate that these differences do not affect safety and effectiveness of the subject device compared to the predicate device.

Non-Clinical Performance Data:

The device's software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The Software Hazard analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria of each module and interaction of processes. The GOLDENEAR COMPANY's TINNITOGRAM™ SIGNAL GENERATOR device passed all testing and supports the claims of substantial equivalence and safe operation.

The referenced FDA guidelines are as follows:

- General Princip les of Software Validation
- Software as a Medical Device (SaMD): Clinical Evaluation
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Clinical Performance Data:

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 874.3400 and based on the analysis and empirical validation of the above information and comparison table, the GOLDENEAR COMPANY, Inc. concludes that the TINNITOGRAM™ SIGNAL GENERATOR is as safe and as effective and substantially equivalent to the predicate device.