June 30, 2023

Duearity AB
Anneli Johansson
Head of QA/RA
Krusegrand 42d
Malmo, 21225
Sweden

Re: K223694
Trade/Device Name: Tinearity G1 (6103); Tinearity G1 Adapters x3 (6042)
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: May 26, 2023
Received: May 26, 2023

Dear Anneli Johansson:

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
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Respiratory, ENT and Dental Devices
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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)*
K223694

Device Name
Tinearity G1

Indications for Use *(Describe)*
Tinearity G1 is intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noise to provide relief for patients with normal hearing in the home healthcare environment. The device is for prescription use only. The target population is adult population over 18 years of age.

Tinearity G1 is applied on intact skin at the mastoid bone and transfers sound through bone conduction to the cochlea. Hearing health care professional shall be consulted for diagnosis, fitting of devices, and follow-up care.

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.

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510(k) Summary

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Date Prepared: 2023-06-29

DEVICE
Name of Device: Tinearity G1
Common or Usual Name: Tinearity Sound Generator
Classification Name: Tinnitus masker
Regulation Number: 21CFR874.3400
Regulatory Class: II
Product Code: KLW

PREDICATE DEVICE
Predicate device: Tranquil TRI-BTE, K061459
This predicate device has not been subject to a design-related recall.

REFERENCE DEVICE
Reference device: ADHEAR System, K172460
This predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION
The Tinearity G1 device is designed to generate sounds to be used in a Tinnitus Management Program to relieve patients suffering from tinnitus.

Tinearity G1 comprises of three components: a sound generator, an adapter and a charger. The sound generator is attached to the skin behind the ear by means of the adapter. The sound generator converts white noise into vibrations that are transmitted via the adapter through the skull to the inner ear. The device generates white noise within the frequency span of 700z-10Khz with a maximum output level of 48dB HL.

The adapter is a disposable device that serves as a mechanical connector between the sound generator and the user. The adapter is made up of a plastic holder that is compatible with the sound generator and a medical grade tape to be attached to the user's skin behind the ear. The adapter is a single use device and is designed to be removed daily after each treatment.

The sound generator uses a re-chargeable battery as power source which is charged with the charger.

The Tinearity G1 sound generator and adapter can be used during all times of the day, during sleep as well as during work and spare time.

INDICATIONS FOR USE

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Tinearity G1 is intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises to relieve patients with normal hearing in a home healthcare environment. The device is for prescription use only. The target population is adult population over 18 years of age.

Tinearity G1 is applied on intact skin at the mastoid bone and transfer sound through bone conduction to the cochlea.

Hearing health care professional shall be consulted for diagnosis, fitting of the device, and follow-up care.

CONTRAINDICATIONS

The device is NOT intended for users suffering from hearing loss or hyperacusis.

POSSIBLE SIDE EFFECTS

The adapter consists of a plastic holder and medical tape. The tape has an acrylic adhesive that adheres the adapter to the user's skin. Irritation may occur behind the ear when replacing the disposable adapter.

White noise may result in worsening tinnitus symptoms. Bone conducted sound may result in headache, nausea and/or dizziness. If any of this occurs, stop using the device and consult your healthcare professional.

USEFUL LIFE / SERVICE LIFE

Useful life of the sound generator is 24 months, calculated from the manufacturing date. Expiration date for the adapter is 24 months as stated on the label.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Tinearity G1 is equivalent to the predicate device in terms of intended use, indications for use, mechanism of action and target organ for the sound.

At a high level the subject and predictive device is based on the same technological elements:

- Sound generator – used to generate sound of sufficient intensity and band width to be used for tinnitus management.
- Device designed to transmit sound to the inner ear.
- Use of broad-band sound that fluctuates in amplitude and frequency.
- Use of a volume control to adjust the volume.

The following main technological differences exist between the subject and the predictive devices:

- The subject device is a bone conducting device. It uses the same operating principle of transferring the sound via the bone of the skull to the inner ear as the reference device ADHEAR System.
- The subject device is attached to intact skin behind the ear with a medical tape. It uses the same principle of attachment as the reference device ADHEAR System.
- The subject device has a slightly different performance output.
- The subject device uses a different power source, a lithium-ion battery.

PERFORMANCE DATA

The following performance and safety data were provided in support of the substantial equivalence determination.

SOUND PERFORMANCE
The performance output of the subject device in form of frequency versus amplitude has been established in the frequency range 100 Hz – 10 kHz. The subject device has its peak frequency at 2kHz with a maximum force output of 48dB HL. The performance output of the subjective device has been studied and compared to the predictive device by use of bench testing. The performance output is identical for the subject device and the predicate device in the overlapping therapy area. Sound performance of the subject device is found to be equivalent to the sound performance of the predicate device.

BIOCOMPATBILITY ASSESSMENT
Biocompatibility assessment was successfully performed on the Tinearity G1 system.

The Tinearity G1 device is intended to be used in contact with intact skin, long term duration.

Production equivalent samples were used during in vitro testing according to;
- Cytotoxicity, ISO 10993-5:2009 and ISO 10993-12:2021
- Sensitization, ISO 10993-10:2021 and ISO 10993-12:2021
- Irritation, ISO 10993-23:2021 and ISO 10993-12:2021.

Production equivalent samples were used during in vivo testing according to;
- Cytotoxicity, ISO 10993-5:2009 and ISO 10993-12:2021
- Sensitization, ISO 10993-10:2021 and ISO 10993-12:2021
- Irritation, ISO 10993-23:2021 and ISO 10993-12:2021.

Within the in vivo irritation test there were 2 rabbits that showed positive results for the irritation in sesame oil extract i.e., 1.2. Moreover, the third rabbit also showed erythema and edema scores for the test SO sites lower than the 2 others, but still higher than the control blank SO sites reactions, confirming the irritant potential of the test article. Review of the device materials, including performed studies on component level, and a survey covering the clinical use of the device (including the first 24 hours) confirm the safe use of the device when used as intended.

The evaluation follows the guidelines;
- 2020 FDA Biocompatibility Guidance. ”Use of International Standard ISO 10993-1, Biological Evaluation of medical Devices Part 1: Evaluation and testing within a risk management process”, Guidance for Industry and Food and Drug Administration Staff, September 2020.”
- Select Updates for Biocompatibility of certain Devices in Contact with Intact Skin.

The performed biological evaluation concludes that all identified biological risks have been adequately addressed for Tinearity G1 system according to ISO 10993-1:2018 and the FDA Biocompatibility Guidance, 2020.

The performed evaluation provides objective evidence to support the conclusion that Tinearity G1 can be considered biocompatible for its intended use.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)
Electrical safety and EMC were successfully performed on the Tinearity G1 system;
- Electrical safety, IEC 60601-1:2005 + AMD1 + AMD2
- Electrical safety, IEC 60601-1-11:2015
- EMC, IEC 60601-1-2:2014-02

HUMAN FACTOR
Human factors were successfully performed on the Tinearity G1 system;

- Usability / Human factor, IEC 60601-1-6:2020

MECHANICAL AND OTHER TESTING
Benching testing was successfully performed on the Tinearity G1 in respect to the defined design specification requirements such as:

- Transport validation, ASTM D4169-16
- Ageing, ASTM F1980-16

The collective results of the non-clinical testing demonstrate that the intended use of Tinearity G1 is substantially equivalent to the predicate device.

POWER SOURCE
The sound generator is driven by a Lithium-ion battery. Lithium-ion batteries are the state-of-the-art electrochemical energy storage technology for hearing devices. During normal use, the battery will last the whole day and there is no risk of interruption in the treatment due to the need of battery change.

CLINICAL TESTING

Clinical testing has been performed in the form of a customer survey to support Real World Evidence (RWE). The clinical testing was conducted on adult subjects with normal hearing suffering from tinnitus. In order to be able to establish the tinnitus frequency and amplitude the included subjects had a pure tinnitus tone. The survey was held as an interview with a pre-defined questioner to investigate immediate relief from the tinnitus sound.

The performed survey shows that subjects with normal hearing suffering from tinnitus can perceive an immediate relief (suppression, masking) from the tinnitus sound with the use of Tinearity G1 when used for masking of tinnitus sound. The survey also indicates that side-effects from the use of Tinearity G1 for masking of a tinnitus sound is very limited.

CONCLUSIONS

The non-clinical and clinical data support that Tinearity G1 does not raise new or different questions of safety or effectiveness, and demonstrates that Tinearity G1 is substantially equivalent to the predicate device, which is currently marketed for the same intended use.