June 10, 2026

Sivantos GmbH
Anja Ravn
Global Senior Regulatory Affairs Specialist
Henri-Dunant-Str. 100
Erlangen, 91058
Germany

Re: K260614
Trade/Device Name: Tinnitus Therapy
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: May 11, 2026
Received: May 11, 2026

Dear Anja Ravn:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260614

Device Name
Tinnitus Therapy

Indications for Use *(Describe)*
The Tinnitus Therapy feature is intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. Tinnitus Therapy feature is intended to be used by those individuals who experience tinnitus and desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do need amplification. This product may also be used with children 5 years of age or older.

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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WSA

510(k) Summary
K260614

1. Submitter

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Contact Person: Anja Ravn, Global Senior Regulatory Affairs Specialist
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Date Prepared: May 11, 2026

2. Subject Device

Device Proprietary Name:	Tinnitus Therapy
Common or Usual name:	Tinnitus Masker
Classification Name:	Tinnitus Masker
Regulatory Number:	21 CFR § 874.3400
Product Code:	KLW
Device Classification:	Class II

3. Predicate Device:

TCI-Combi Tinnitus Masker (cleared under K003558)

3.1. Reference Devices:

Sound Options Tinnitus Treatment (cleared under K161562)
Tinnitus Sound Generator Module (cleared under K180495)

4. Device Description

The Tinnitus Therapy is intended for use by people with tinnitus who may also desire amplification. The feature is based on the predicate device TCI-Combi Tinnitus Masker (K003558) and references the Sound Options Tinnitus Treatment (K161562) and Tinnitus Sound Generator Module (K180495). Tinnitus Therapy is embedded in a Class II, 510(k)-exempt wireless air conduction hearing aid regulated under 21 CFR § 874.3305.

Tinnitus Therapy feature is activated and fitted by a Hearing Care Professional (HCP) via dedicated fitting software and can be adjusted locally by the user via a dedicated mobile application, remote-control unit or on the hearing aid.

Tinnitus Therapy offers two approaches to tinnitus management and can be used as part of a tinnitus management program:

- Generated sound stimuli that can be modulated and adjusted to the patient's needs (Sound Therapy for various types of tinnitus).
- Spectral notching of amplified stimuli that can be adjusted according to the patient's needs (Notched Amplification Therapy for tonal tinnitus).

5. Indications for Use

The Tinnitus Therapy feature is intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. Tinnitus Therapy feature is intended to be used by those individuals who experience tinnitus and desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do need amplification. This product may also be used with children 5 years of age or older.

6. Comparison of Technological Characteristics

Both the subject and predicate device are Tinnitus Maskers indicated for adults 18 years of age or older with tinnitus and may also be used from the age of 5 years or older. Both devices utilize the same fundamental technology, enabling users to control and personalize the device to their needs. Both are embedded in 510(k)-exempt air-conduction hearing aids.

At a high level, the subject and predicate devices share the following technological elements:

- Sound stimuli provided to relieve patients suffering from tinnitus.
- Activation of the tinnitus feature is done by a qualified HCP.
- Home healthcare environment use.

The primary design differences between the subject and predicate devices include:

- Additional types of sounds and frequency shaping.
- Integration into wireless, 510(k)-exempt hearing aids.
- Support for use across a wider range of 510(k)-exempt hearing aid styles.

A detailed comparison table of key features for the subject, predicate, and reference devices is provided below.

Comparison of Subject and Predicate/Reference Devices

	"Tinnitus Therapy" (Subject device)	"TCI-Combi" (Predicate: K003558, own device)	"Sound Options Tinnitus Treatment" (Reference: K161562)	"Tinnitus Sound Generator Module" (Reference: K180495)	Equivalence Discussion
Regulation	21 CFR 874.3400	21 CFR 874.3300, 21 CFR 874.3400	21 CFR 874.3400	21 CFR 874.3400	Same
Product code	KLW	ESD, KLW	KLW	KLW	Same
Indications for Use	The Tinnitus Therapy feature is intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. Tinnitus Therapy feature is intended to be used by those individuals who experience tinnitus and desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.	The TCI-Combi is a behind-the-ear style electronic, air conduction broadband noise generator and hearing aid intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. TCI-Combi is intended to be used by those individuals who experience tinnitus and desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.	N/A	N/A	Same
User Population	The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do need amplification. This product may also be used with children 5 years of age or older.	The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do need amplification. This product may also be used with children 5 years of age or older.	N/A	N/A	Same.
Technological Characteristics	Embedded in 510(k)-exempt wireless air-conduction hearing aid. Enabled with hearing aid programming software in the clinic or remotely. Can be adjusted via a dedicated medical mobile application.	Embedded in 510(k)-exempt air-conduction hearing aid. Enabled with hearing aid programming software.		Embedded in 510(k)-exempt wireless air-conduction hearing aid. Enabled with hearing aid programming software in the clinic or remotely. Can be adjusted via a dedicated medical mobile application.	Same technological characteristics as predicate. The implemented modification to embed the tinnitus feature in a wireless hearing aid enables both TeleCare and adjustments via the app and is the same as for reference device K180495.

	"Tinnitus Therapy" (Subject device)	"TCI-Combi" (Predicate: K003558, own device)	"Sound Options Tinnitus Treatment" (Reference: K161562)	"Tinnitus Sound Generator Module" (Reference: K180495)	Equivalence Discussion
Principle of Operations	Tinnitus Sound Therapy provides sound stimuli that can be modulated and adjusted to a patient's stimulus needs. Can be programmed with noise in a separate program or in a program combined with amplification. Tinnitus Notch Therapy provides patients suffering from hearing loss and tonal tinnitus with the option of spectral notching of the amplified sound based on a patient's audiological data and pitch match.	The TCI-Combi provides sound stimuli that can be modulated and adjusted to a patient's stimulus needs. Can be programmed with noise in a separate program or in a program combined with amplification.	Qualified health care professionals provide Sound Options with patients' hearing thresholds, tinnitus type (tonal, ringing, or hissing), and pitch match. Using each patient's audiogram and tinnitus frequency, the SO 2.0 software modifies frequency-specific amplitudes in music tracks to create customized, music-based sound therapy. OTS software is used to equalize the average volume across tracks before delivery. Patients receive their customized music by downloading or CD and listen at a comfortable volume using their personal audio device.	N/A	For sound therapy, the principle of operation is the same as for predicate device. The addition of customization of the spectral content, Notch Therapy, is comparable to that of reference device K161562.
Maximum Output of generated sound	Tinnitus Therapy is embedded in the patient's hearing aid. Maximum output depends on hearing aid style and hearing loss of patient.	102 dBA.	N/A	N/A	Maximum output level is measured using the same methods.

7. Performance Testing

In accordance with IEC 62304, Tinnitus Therapy is deemed Class A.

Tinnitus Therapy complies with relevant sections of the standards listed below and FDA special controls through adequate risk management, software verification and validation to requirement specifications, and adequate labeling. These activities collectively demonstrate that the device is as safe and effective as the predicate and reference devices.

- IEC 62304 A1:2016 Medical device software - Software life cycle processes
- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- ANSI/ASA S3.5-1997 (Reaffirmed 2020) American National Standard Methods for Calculation of the Speech Intelligibility Index
- § 21 CFR 874.3400 Tinnitus masker - Special Controls for patient labeling

The fundamental approach used to provide tinnitus relief through sound stimuli is consistent with that of the predicate TCI-Combi. Although Tinnitus Therapy includes minor updates, such as additional sound types, modified frequency shaping, and integration into a broader range of hearing aid styles, these differences do not change the technological characteristics. No new clinical performance testing was required.

8. Conclusion

The Tinnitus Therapy is as safe and effective as the predicate TCI-Combi Tinnitus Masker (K003558). The Tinnitus Therapy has the same indications for use, and similar technological characteristics and principles of operation as its predicate and reference devices. In addition, the minor differences between the subject and predicate/reference devices raise no new issues of safety or effectiveness. Therefore, the Tinnitus Therapy is substantially equivalent to the predicate device.