August 13, 2026

Levo Medical Corporation
% Tal Bersler Stramer
Principal Consultant
SpringRA, Inc.
325 Betty Ann Dr., North York
ON M2R 1B4 CAN

Re: K260413
Trade/Device Name: Levo Gen 2 Tinnitus Therapy System
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: July 17, 2026
Received: July 17, 2026

Dear Tal Bersler Stramer:

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,

SRINIVAS NANDKUMAR -S

Srinivas Nandkumar, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260413

Please provide the device trade name(s).

Levo Gen 2 Tinnitus Therapy System

Please provide your Indications for Use below.

The Levo Gen2 is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older).

This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary for Levo Medical's

Date Prepared: 30 June 2026

1. Submitter

Company Name: Levo Medical Corporation
Address: 455 Boleskine Road, Victoria, BC, Canada, V8Z 1E7
E-mail: info@levomedical.com

Contact Person:
Name: Ms. Tal Bresler Stramer, RA Consultant
Company: SpringRA Inc.
E-mail: info@springra.com

2. Device:

Name of Device: Levo Gen 2 Tinnitus Therapy System
Common or Usual Name: Levo Gen 2 Tinnitus Therapy System
Classification Name: Tinnitus Masker Device, 21 CFR 874.3400
Regulatory Class: II
Product Code: KLW

3. Predicate and Reference Devices:

Predicate device: Aureliym's SilentCloud (K221125)

Reference device: LEVO TINNITUS MASKING SOFTWARE DEVICE (K140845)

4. Device Description

The Levo Gen 2 Tinnitus Therapy System (hereafter "Levo Gen2") is a software-based medical device that combines individualized tinnitus sound masking therapy, configured specifically for the patient by a healthcare professional (HCP), with a Continuous Learning Platform (CLP) that incorporates tinnitus education, standardized tinnitus questionnaires (e.g., Tinnitus Handicap Inventory (THI), Tinnitus Functional Index (TFI)), and a structured habituation program informed by principles of cognitive-behavioral therapy (CBT) and mindfulness-based interventions. Together, these two therapeutic modalities are intended to reduce the impact of tinnitus and the distress associated with tinnitus perception.

The LEVO Gen2 is a software-based medical device implemented as a single iOS application distributed via the Apple App Store and installed on compatible Apple iPad and iPhone devices running iOS 26 and iPadOS 26. The application provides different functional interfaces based on user authorization.

When accessed by a HCP, the application enables Levo Gen2 Manager functionality to characterize patient's perceived tinnitus, configure and prescribe personalized sound therapy for use during sleep, enable the CLP platform and monitoring therapy progress over time.

When accessed by a *patient*, the same application enables Levo Gen2 Patient functionality, which is limited to receiving and playing prescribed acoustic therapy programs and to access the Continuous Learning Platform (CLP). CLP content is made available to the patient in a staged, sequential manner. User access and available functionality are controlled through role-based authorization mechanisms.

For playback of therapy content, patients use the Levo Gen2 with commercially available earbuds that are compatible with the application, including AirPods (3rd or 4th generation), AirPods Pro (1st, 2nd or 3rd generation), EarPods or Beats Fit Pro (hereafter "compatible earbuds").

The Levo Gen2 system generates therapeutic acoustic stimuli - pure tones, cricket-like patterned tones, white noise, and narrow-band (bandpass) noise - for use in tinnitus masking therapy

Intended Use / Indications for Use

The Levo Gen2 is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older).

This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

5. Summary of Technological Characteristics

The Levo Gen 2 and the predicate device, SilentCloud (K221125), share the same fundamental technological characteristics and principles of operation. Both the subject and predicate devices are prescription-only tinnitus relief software applications that combine individualized acoustic sound therapy, configured for the patient by an HCP, with a CBT-based tinnitus education and habituation program delivered under HCP oversight. Both consist of two software modules, a *patient-facing* application for therapy administration and an *HCP-facing* management application for patient evaluation, therapy configuration, and oversight. In both, management functionality is restricted to authorized HCPs through software access controls that prevent the patient from generating or modifying therapy parameters. In both systems, the HCP customizes the sound therapy and screens the patient for applicability of the CBT-based module. The HCP is responsible for deciding whether the patient is eligible for the treatment. Both systems follow a similar clinical workflow (evaluation questionnaires, an interactive sound matching step, HCP-supervised sound therapy and a staged CBT program), both support independent left and right ear volume adjustment, and both comply with applicable sound output safety standards within the human audible frequency range.

The subject and predicate devices have minor technological differences as listed below. None of these differences raises different questions of safety or effectiveness:

- Platform and distribution. The subject device runs on Apple iOS/iPadOS with both modules distributed through the Apple App Store; the predicate runs on iOS and Android with a web-based HCP module. This is an implementation difference; the HCP retains exclusive control over therapy parameters in both devices.
- Sound generation. The subject device builds masking sound from pure tones, white noise, and narrow-band noise (SAM-capable), with up to eight simultaneous sound generators; the predicate uses broadband-noise and tonal masking. Both use standard, well-established tonal and noise stimuli within the same audible range and output limits.
- Maximum output. The subject device is capped at 85 dB SPL, below the predicate's limit of up to 110 dB, reducing rather than increasing acoustic-exposure risk.

- Output frequency. The subject device operates from 125 Hz to 16 kHz versus the predicate's 100 Hz to 15 kHz. Both fall within the human audible range, output is capped at 85 dB SPL, and the difference does not affect clinically acceptable masking.
- Maximum treatment duration. The subject device permits up to 8 hours per day versus 4 hours for the predicate. Because output is capped at 85 dB SPL, cumulative exposure over 8 hours remains within the OSHA permissible occupational noise-exposure limit (90 dBA, 8-hour time-weighted average).
- Treatment timing. The subject device is used during sleep only, a narrower window that falls within the predicate's cleared day-and-night timing and reduces patient risk.
- CBT-based program structure. The subject device's CLP delivers the same therapeutic domains as the predicate's iCBT program through a different number of modules; the difference is one of delivery format, not therapeutic intent or mechanism of action.

The subject device was verified through bench performance testing and software verification and validation to confirm it meets its specifications, including the 85 dB SPL output limit. On this basis, the technological differences between the Levo Gen 2 and the predicate device do not raise different questions of safety or effectiveness.

The Levo Gen 2 sound-masking function is based on the same masking technology as its predecessor, the Otoharmonics Levo System (K140845), which is cited as a reference device and was also the reference relied upon by the predicate to characterize its broadband-noise masking.

A table comparing the key features of the subject and predicate devices is provided below.

Table 1: Technological Characteristics Comparison

	Proposed Levo Gen2 (K260413)	**Predicate device: SilentCloud (K221125)**	**Reference device Levo System (K140845)**	**Comparison / Discussion**
General Purpose	Therapeutic software application for treatment of chronic tinnitus in combination with a CBT-based Tinnitus Management Program	Therapeutic software tool for treatment of chronic subjective tinnitus in combination with a Tinnitus Management Program	Sound masking therapeutic software application for treatment of chronic tinnitus	Same. Both are therapeutic software applications for the treatment of chronic subjective tinnitus delivered within a tinnitus management program.
Indications for Use	The Levo Gen2 is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population	The *SilentCloud* in combination with a Tinnitus Management Program is a therapeutic software tool for the treatment of chronic subjective tinnitus for home use. The target population for the *SilentCloud* System are adult tinnitus patients over 18 years.	The Levo System is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population	Same intended use. Both are indicated for the relief of tinnitus symptoms in adults 18 years of age or older, prescribed and configured by a qualified HCP. Decision Points 1 and 2 are satisfied.

	Proposed Levo Gen2 (K260413)	Predicate device: SilentCloud (K221125)	Reference device Levo System (K140845)	Comparison / Discussion
	is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.	The *SilentCloud* System is intended to provide relief from the disturbance of chronic subjective tinnitus while using the device.	is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.	
Therapeutic Modalities	(1) Individualized tinnitus sound masking; (2) Continuous Learning Platform (CLP) incorporating CBT-based content (attention training, emotional coping, stress reduction, sleep hygiene)	(1) Individualized acoustic sound therapy (tonal + broadband noise masking); (2) Education & counseling + cognitive behavioral therapy (iCBT)	(1) Individualized tinnitus sound masking;	Same modalities. Both combine individualized, HCP-configured tinnitus sound masking with a CBT-based tinnitus education and habituation program. Differences in delivery format do not alter the therapeutic intent and do not raise different questions of safety or effectiveness.
Condition Treated	Chronic subjective tinnitus	Chronic subjective tinnitus	Chronic subjective tinnitus	Same. Chronic subjective tinnitus.
Use Setting	Home use	Home use	Home use	Same. Home use.
Patient Population	Adults ≥18 years	Adults ≥18 years	Adults ≥18 years	Same. Adults 18 years of age or older.
HCP Requirement	Prescription only; prescribed by qualified HCP; patient completes therapy at home	Prescription only; fitted and programmed by qualified HCP; patient uses at home	Prescription only; fitted and programmed by qualified HCP; patient uses at home	Same. Prescription-only; therapy is prescribed and configured by a qualified HCP and completed by the patient at home. Management functionality is restricted to authorized HCPs through software access controls in both devices.
Regulatory Classification	Class II, 21 CFR 874.3400, KLW	Class II, 21 CFR 874.3400, KLW	Class II, 21 CFR 874.3400, KLW	Same. Class II, 21 CFR 874.3400, product code KLW.
Type of Use	Rx only	Rx only	Rx only	Same. Prescription (Rx) only.
Patient medium	Software only	Software only	Hand-held audio device (iPod touch®) for use with custom earbuds	Same. Both are software-only and rely on patient-obtained compatible audio hardware.
Architecture / platform	Two software modules (Levo Manager, Levo Patient) on compatible Apple iOS/iPadOS devices	Two software modules: patient mobile application (Apple iOS or Android) and web-based HCP Dashboard	Two software modules: Levo Manager software supplied preinstalled on iPad® or iPad Air Levo Patient software supplied preinstalled on iPod touch	Both consist of two software modules: a patient-facing therapy application and an HCP-facing management application. The platform difference (subject device on Apple iOS/iPadOS with an app-store-distributed

	Proposed Levo Gen2 (K260413)	Predicate device: SilentCloud (K221125)	Reference device Levo System (K140845)	Comparison / Discussion
			Earbuds Accessories (standard Apple® charger with Apple® device)	Manager; predicate on iOS/Android with a web-based HCP Dashboard) reflects an implementation variation. The HCP retains exclusive control over delivered therapy parameters in both devices, so the difference does not raise different questions of safety or effectiveness.
Sound output	Sounds customized to the patient by qualified health care professional. From 1 to eight (8) combinations of the following sounds: Pure Tone White Noises Narrow Band Noises (bandwidth selectable by HCP) Includes the ability to create sinusoidal amplitude modulated (SAM) tones.	Broadband-noise masking (characterized by the manufacturer as technologically comparable to the Levo System reference device) and tonal sound therapy	Sounds customized to the patient by qualified health care professional. From 1 to ten (10) combinations of the following sounds: Pure Tone White Noises Narrow Band Noises (bandwidth selectable by HCP) Includes the ability to create sinusoidal amplitude modulated (SAM) tones.	Both produce individualized, HCP-configured masking sound built from standard, well-established tonal and noise stimuli within the human audible range and subject to the applicable output limits. The predicate characterized its broadband-noise masking against the Levo System reference device (K140845); the subject device characterizes its masking output against the same reference at Decision Point 5a. The synthesis options differ in detail but do not introduce a new therapeutic modality or new risk, and therefore do not raise different questions of safety or effectiveness. (See Sections 3.5 and 3.6.)
Data logging	Yes	Yes	Yes	Same. Both log therapy and adherence data, with appropriate safeguards applied to storage and transmission.
Therapy transmission	Cloud-based	Cloud-based	Direct wireless transfer	Same. In both devices the HCP-customized therapy is delivered to the patient device through a cloud-based infrastructure. Neither device requires continuous internet connectivity during therapy administration.
Volume control	Independent per-ear	Independent per-ear	Independent per-ear	Same. Independent left- and right-ear volume

	Proposed Levo Gen2 (K260413)	Predicate device: SilentCloud (K221125)	Reference device Levo System (K140845)	Comparison / Discussion
				adjustment. In both devices output volume is the only patient-adjustable parameter and is bounded by HCP-programmed limits.
Maximum output	85 dB SPL	Up to 110 dB	85 dB SPL	The subject device output ceiling of 85 dB SPL is lower than the predicate limit of up to 110 dB, which reduces rather than increases acoustic-exposure risk. The difference does not raise different questions of safety or effectiveness.
Output frequency	125 Hz to 16 kHz	100 Hz to 15 kHz	125 Hz to 16 kHz	Subject device 125 Hz to 16 kHz versus predicate 100 Hz to 15 kHz. Both ranges fall within the human audible range, output is capped at 85 dB SPL, and exclusion of the 100 to 124 Hz band does not affect clinically acceptable masking. The 16 kHz upper boundary lies within the established output range of the Levo System masking technology referenced by both devices. The difference does not raise different questions of safety or effectiveness.
Maximum treatment duration	8 hours per day	4 hours per day	8hours per day	Subject device permits up to 8 hours per day versus 4 hours for the predicate. Because subject device output is capped at 85 dB SPL, cumulative exposure over 8 hours remains within the OSHA permissible occupational noise-exposure limit (90 dBA, 8-hour time-weighted average). The longer window therefore does not increase risk or raise different questions of safety or effectiveness.
Treatment timing	Night (sleep) only	Day and night	Day and night	Subject device is used during sleep only; the predicate may be used during both wakefulness

	Proposed Levo Gen2 (K260413)	Predicate device: SilentCloud (K221125)	Reference device Levo System (K140845)	Comparison / Discussion
				and sleep. The narrower sleep-only window falls within the predicate cleared treatment timing and reduces patient risk (e.g., the predicate warns against use while driving or operating machinery). The difference does not raise different questions of safety or effectiveness.

6. Performance Data:

Software verification and validation testing was performed per IEC 62304:2015 Medical device software - Software life cycle processes to demonstrate safety and performance based on current industry standards.

In addition, the following nonclinical bench testing was conducted to validate the performance of the LEVO Gen2 System and ensure the device performs as intended and meets the design specifications:

- **Acoustic Calibration test**
- **Battery Endurance test**

In all instances, the Levo Gen2 functioned as intended.

7. Conclusions

The Levo Gen2 and the predicate/reference devices have the same intended uses and indications, principle technological characteristics, and principles of operation. The minor technological differences between the Levo Gen2 and its predicate/reference devices are addressed by the performance testing described above and do not introduce different questions of safety or effectiveness. Therefore, we can conclude that these devices are substantially equivalent.