February 27, 2024

PNQ Health
% Alexia Haralambous
Senior Principal
Rqm+
2251 San Diego Avenue
Suite B-257
San Diego, California 92110

Re: K233435
Trade/Device Name: Peace N Quiet (0.7.0)
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: January 29, 2024
Received: January 29, 2024

Dear Alexia Haralambous:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233435

Device Name

Peace N Quiet (0.7.0)

Indications for Use *(Describe)*

The Peace N Quiet device is indicated for use in the temporary relief of tinnitus symptoms. The device plays customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is for patients who are 18 years or older. This device should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

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

DATE PREPARED
February 23, 2024

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DEVICE INFORMATION
Proprietary Name/Trade Name: Peace N Quiet
Common Name: Tinnitus masker
Regulation Number: 21 CFR 874.3400
Class: II
Product Code: KLW
Premarket Review: Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1), Division of Dental and ENT Devices (DHT1B)
Review Panel: Ear, Nose, and Throat

PREDICATE DEVICE IDENTIFICATION
The Peace N Quiet device is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*	*Reference Device*
K161562	Sound Options Tinnitus Treatment / Sound Options Tinnitus Treatments, Inc.	✓	
K163094	TinniLogic Mobile Tinnitus Management Device / Jiangsu BetterLife Medical, Ltd.		✓

DEVICE DESCRIPTION

The Peace N Quiet tinnitus device is software as a medical device implemented as a mobile application for patients suffering from tinnitus. The Peace N Quiet tinnitus mobile app can be downloaded from the Apple Store onto a personal Apple iPhone device. The device facilitates a qualified healthcare professional (HCP), i.e., physician or audiologist, to provide professional counseling or education to the patient. The HCPs can direct and assist patients to self-administer customized treatments using the Peace N Quiet tinnitus device.

INDICATIONS FOR USE

The Peace N Quiet device is indicated for use in the temporary relief of tinnitus symptoms. The device plays customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is for patients who are 18 years or older. This device should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

PNQ Health, Inc. believes that the Peace N Quiet device is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use as the primary predicate, the Sound Options Tinnitus Treatment (K161562), i.e., software intended for the temporary relief of tinnitus symptoms, with a target population of patients who are 18 years or older and suffering from tinnitus. The subject device shares several technological characteristics with the primary predicate (K161562). Both are software-only medical devices that provide audio sound outputs customized to the patient to mask tinnitus as part of a tinnitus management program, and both systems are compatible with pre-specified earbuds (non-medical device). The subject device differs in that its sounds are customized to the patient by a qualified HCP, whereas the primary predicate (K161562) has sounds that are primarily customized by the device manufacturer (Sound Options Tinnitus Treatments, Inc.) in addition to the HCP. Both allow for physical volume control and maintain the same output maximum, 85 dBA, with similar output frequency ranges that fall within normal human hearing frequency ranges. In addition, both utilize primarily amplitude-modulated stimuli. The primary predicate (K161562) relies on broadband frequency sound prescribed and customized to the patient by the HCP, whereas the subject Peace N Quiet device includes frequency modulation (in addition to amplitude modulation) that is customized to the patient within the device by a qualified HCP. The periodic signal types offered by the subject device provide additional options for HCP and patient customization of tinnitus-matched sounds. To allow the HCP and patient to further tailor the customized sounds to match the patient's perceived tinnitus, the primary predicate (K161562) uses broadband noise adjustments, while the subject device offers the user the option of additive pseudorandom noise adjustments such as white or pink noise. Both sets of options offer the user ways to tailor the customized sounds to come as close as possible to the patient's perceived tinnitus, with the subject device offering a higher number of adjustable parameters as compared to the primary predicate.

The TinniLogic Mobile Tinnitus Management Device (K163094) device was used as a reference device to support the technology of temporary relief of tinnitus symptoms through customized

masking sounds. The reference device (K163094) utilizes sinusoidal amplitude-modulated sounds with a combination of narrow-band noise, broad-band noise, and other types of noise such as white noise and natural sounds, to allow the user ways to tailor the customized sounds. These options differ slightly from the additive noise options of the subject device, but both the reference device (K163094) and primary predicate noise options offer the user a variety of options intended to allow them to match the patient's perceived tinnitus as closely as possible. These differences do not present new or modified risks, and therefore they do not raise different questions of safety and effectiveness. This information is summarized in the following table.

	Subject Device: Peace N Quiet	**Primary Predicate: Sound Options Tinnitus Treatment (K161562)**	**Reference Device: TinniLogic Mobile Tinnitus Management Device (K163094)**
Indications for Use	*The Peace N Quiet device is indicated for use in the temporary relief of tinnitus symptoms. The device plays customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is for patients who are 18 years or older. This device should only be used with the advice of a physician, audiologist or other hearing healthcare professional.*	*The device, Sound Options Tinnitus Treatment, version SO 2.0, is for the temporary relief of tinnitus symptoms. The device is a software application that embeds sounds and spectral content into music to relieve patients suffering from tinnitus and can be used as part of a tinnitus management program for adults 18 years and older. The device is for prescription use by a physician, audiologist or other healthcare professional.*	*The TinniLogic Mobile Tinnitus Management Device is indicated for use in the temporary relief of tinnitus symptoms. The device is a player to play customized sounds and display professional counseling or education 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.*
Target Population	Adult (18 years and older) tinnitus patients	Adult (18 years and older) tinnitus patients	Adult (18 years and older) tinnitus patients
Use Environment	At-home and healthcare facilities	At-home and healthcare facilities	At-home and healthcare facilities
Patient Medium	Software only	Software only	Hand-held audio device for use with earphones
Professional Counseling/ Education	Guidance is provided via the HCP and prompts on the software app	Guidance is provided via the HCP	Guidance is provided via the HCP as well as prompts on the provided tablet
Device Components	Peace N Quiet Software	• Sound Options software only device, SO 2.0	• TinniLogic Mobile Tinnitus Management Device with software pre-installed

	Subject Device: Peace N Quiet	**Primary Predicate: Sound Options Tinnitus Treatment (K161562)**	**Reference Device: TinniLogic Mobile Tinnitus Management Device (K163094)**
			• Earphones • Accessories (adaptor, power cable, USB cable)
Sounds	Sounds customized to the patient by a qualified health care professional.	Sounds customized by Sound Options Tinnitus Treatments, Inc. (manufacturer) Customized music tracks are available to patients by download or on CD.	Sounds customized to the patient by a qualified healthcare professional.
Stimuli Type	Periodic Signal • Type (Sine, Triangle, Sawtooth, Square) • Amplitude • Frequency • Phase • Duty Cycle (for square type only) Pseudorandom • Type (Random, Pseudorandom) • Random Noise Type (White, Pink) • Amplitude • Frequency Limits (Low & High) Modulation • Amplitude (A signal played at various amplitudes) • Frequency (A signal played at various frequencies) • Pulse (A signal that is pulled on and off)	• Amplitude-modulated tinnitus matching • Broadband frequency sound • Broadband noise	• Sinusoidal amplitude modulated (SAM) tinnitus pitch matched sounds • Narrow-band noise centered at the tinnitus frequency • Broad-band noises • Pure tone • White noise • Natural sounds • Relax sounds
Volume Control	Individual volume control per ear of the application software	Patients are to listen to the sound therapy at a comfortable volume level	Individual volume control per ear of the application software

	Subject Device: Peace N Quiet	Primary Predicate: Sound Options Tinnitus Treatment (K161562)	Reference Device: TinniLogic Mobile Tinnitus Management Device (K163094)
		by adjusting the volume control on their personal music-playing device. Safe levels were determined through bench testing for each of the recommended commercial device options described in the user manuals.	Physical volume controls
Maximum Output	85 dB	85 dB	90 dB
Output Frequency	500 Hz~16,000Hz	Dependent on patient headphones (commercial)	50Hz ~15,000Hz
Performance Testing	• IEC 62304:2015	• IEC 62304:2006	• IEC 60601-1 • IEC 60601-1-2

SUMMARY OF NON-CLINICAL TESTING

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.

SUMMARY OF CLINICAL TESTING

Clinical testing was not performed as part of this submission.

CONCLUSION

Based on the verification and validation testing performed in accordance with IEC 62304:2015, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The Peace N Quiet device is demonstrated to be substantially equivalent to the predicate device.