October 27, 2023

hearX SA (Pty) Ltd
Seline Van Der Wat
Chief Operating Officer
Building 2, Ashlea Gardens Office Park, 180 Garsfontein Road
Ashlea Gardens
Pretoria, 0081
South Africa

Re: K231545
Trade/Device Name: hearOAE
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: September 22, 2023
Received: September 22, 2023

Dear Seline Van Der Wat:

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.

510(k) Number *(if known)*
K231545

Device Name
hearOAE

Indications for Use *(Describe)*
hearOAE is intended to be used by hearing healthcare professionals in the audiologic evaluation and documentation of ear function and ear disorders using Transient Evoked Otoacoustic Emissions (TEOAEs) and Distortion Product Otoacoustic Emissions (DPOAEs). The target population for the hearOAE includes all ages.

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

1. SUBMITTER

Name: hearX SA (Pty) Ltd
Address: Building 2, Ashlea Gardens Office Park, 180 Garsfontein Road, Ashlea Gardens, Pretoria, South Africa, 0081
Establishment Registration Number: 3014337591
Contact Person: Seline van der Wat, Chief Operating Officer, Senior Director of Regulatory, Governance & Intelligence
Phone: +27 12 030 0268
Email: Compliance@hearxgroup.com
Date Prepared: 29 May 2023

2. SUBJECT DEVICE

Name of Device: hearOAE
Common or Usual Name: Otoacoustic Emission Device
Classification Name: Audiometer - Otoacoustic Emission (21 CFR 874.1050)
Regulation Class: Class II
Product Code: EWO
Assigned K-number: K231545

3. PREDICATE DEVICE

Otodynamics ILO288 Echoport Plus OAE System (K983350)

4. DEVICE DESCRIPTION

Per 21 CFR 874.1050, the hearOAE (otoacoustic emission device) is a portable, handheld, battery-operated device that can detect hearing loss using Otoacoustic Emission technologies. The hearOAE device may be configured to support one or any combination of TEOAE or DPOAE. Otoacoustic Emission devices are class II medical devices.

hearOAE consists of three main components listed below:

- hearOAE Application (available on supported Android devices supplied by hearX)
- hearOAE Codec
- hearOAE Probe

The hearOAE Application:

- is operated on an Android smart device that uses Bluetooth connectivity to communicate with the hearOAE Codec.
- enables the user to choose and set up testing protocols for both TEOAE and DPOAE.
- enables the checking of the probe functionality, namely “Probe Check”.

- controls the start and stop of a TEOAE and DPOAE test including pre-test functions such as Probe Check and in-ear calibration.
- provides feedback during and after the test in the form of tables, figures, and graphs.

The hearOAE Codec:

- consists of hardware and software for generating the test signals and measuring the responses.
- has the ability to generate, measure and process signals.
- contains a rechargeable lithium-ion battery to power the device.
- uses three light indicators to provide a visual display of the status of the hearOAE Codec to the user. A push button (signified by a Power symbol) is located on the case of the hearOAE Codec to allow the user to switch it on or off.
- communicates the test results via Bluetooth to the hearOAE smart device which will be displayed on the Smart device screen to the user within the application.

The hearOAE Probe:

- houses the speakers (drivers), and a microphone that produces the test stimuli and measures the sound pressure level (SPL) present in the ear canal.
- has a removable probe coupler with ear tips which fit onto the probe coupler.

5. INTENDED USE / INDICATIONS FOR USE

hearOAE is intended to be used by hearing healthcare professionals in the audiologic evaluation and documentation of ear function and ear disorders using Transient Evoked Otoacoustic Emissions (TEOAEs) and Distortion Product Otoacoustic Emissions (DPOAEs). The target population for the hearOAE includes all ages.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The hearOAE has the same intended use and target population as the predicate, Otodynamics ILO288 Echoport plus OAE System (K983350).

A substantial comparison has been performed which provides evidence that facilitates the determination of substantial equivalence between the hearOAE device and the Otodynamics ILO288 Echoport plus OAE System.

Although the specific components of the device may look different, and the devices may be handled differently, both devices are made up of the same components:

- Probe

    - Contains 2 drivers and 1 microphone
    - Small size to fit into a newborn's ear
    - Different sized ear tips that enables the probe to fit small to large ear canal sizes

- Processing unit - hearOAE Codec and Echoport USB
    - Accepts parameters and instructions from user controlled device (laptop and smartphone respectively) and executes OAE tests accordingly
    - Generates and measures the electrical signals sent to and from the probe
    - Processes the measured signals and provides feedback to the user controlled device which is used to update the user interface

- User controlled interface - laptop and smart device
    - Provides a user interface with user input capabilities
    - Provides the user with means to setup test protocols and parameters
    - User can start and stop tests

The non-clinical performance testing results (described in the table in section 7 below) demonstrate that both devices perform equivalently when set to the same protocol and parameters, when testing in similar environments and patients. Additionally, both devices are able to identify the connected probe and provide the means to perform a self-check by inserting the probe into a cavity, presenting and capturing sound, and comparing it to previous data points.

In terms of safety and technical compliance, both devices were tested and evaluated according to the same standards as described in section 8 below.

Differences were addressed through clinical testing (see section 8) and non-clinical performance testing (see section 7). These differences are not significant and do not change the effectiveness or safety of the subject device.

7. NON-CLINICAL PERFORMANCE TESTING:

Performance testing was conducted on the hearOAE to provide a reasonable assurance of safety and effectiveness of the device as compared to Otodynamics

ILO288 Echoport plus OAE System (K983350). The results are summarized in the table below:

Test Standard/Method	**Test Purpose**	**Result**
IEC 60645-6:2022 "Electroacoustics – Audiometric equipment – Part 6: Instruments for the measurement of otoacoustic emissions,"	Requirements for the measurements of otoacoustic emissions	Pass
IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Basic Safety and Essential Performance	Pass
IEC 60601-1-2:2014 Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	Electromagnetic Compatibility	Pass
ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. FDA Guidance FDA-2013-D-0350- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process" - September 4, 2020	Biocompatibility	Pass
IEC 62304:2006+A1:2015 Medical device software – Software lifecycle processes FDA Guidance FDA-2020-D-0957 - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - May 11, 2005	Software Verification and Validation	Pass
FDA Guidance FDA-2018-D-3443 - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - October 18, 2018	Cybersecurity Compliance	Pass

FDA Guidance FDA-2015-D-5105 - Post market Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - December 28, 2016		
IEEE / ANSI C63.27:2017 - Evaluation of Wireless Coexistence AAMI TIR 69:2020 - Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems	Bluetooth SIG Compliance	Pass

The range of testing and all acceptable criteria are appropriate to evaluate this device based on its proposed intended use. All acceptance criteria were met.

8. CLINICAL STUDIES

The current investigation aimed to (a) evaluate the performance of the hearOAE device in testing diagnostic DPOAEs and TEOAEs in adults, and (b) to evaluate the diagnostic agreement of the device for hearing screening in infants in comparison to a commercially available device (Otodynamics IL0288 ECHOPORT Plus OAE System).

Methodology

The investigation followed a cross sectional, within-subject repeated measures design in order to evaluate the performance of the hearOAE device compared to the predicate in both adult and infant participants. Two modalities of testing were used, namely transient evoked otoacoustic emissions (TEOAE) and distortion product otoacoustic emissions (DPOAE).

For sub-aim A, adult participants were recruited and underwent diagnostic DPOAE testing in one ear and TEOAE testing in the opposite ear with both devices. In addition, the diagnostic OAE test with each device was repeated in each ear in order to determine test-retest reliability to allow for comparison of reliability.

Users of the device were qualified and Health Professions Council of South Africa (HPCSA) registered audiologists with prior knowledge of ears and hearing as well as prior OAE device experience. They were trained with the specific hearOAE model to ensure competent use with the device.

Counterbalancing techniques were used during diagnostic testing (adults) and screening (infants). The participants' ears were tested randomly, and the sequence of the tests performed on each participant followed a Latin square design.

For sub-aim B, infants were recruited via consent of their caregivers from the newborn hearing screening (NHS) program at three public healthcare hospitals. Screening TEOAEs for 50% of infant ears (using both the hearOAE and the predicate device) and screening DPOAEs for 50% of infant ears (using both the hearOAE and the the predicate device) were conducted using a counterbalancing

procedure. In this way, diagnostic agreement of the investigator device and comparator device for screening TEOAEs and DPOAEs was measured.

Number of patients (planned and analyzed)

Planned number of participants

For sub-aim A: 50 adults with normal hearing (100 ears) and 25 adults with hearing loss (50 ears). *For sub-aim B:* 350 infant ears (screen 175 ears with DPOAE with both the investigational and comparator device and screen 175 ears using TEOAEs with both the investigational and comparator device).

Analyzed number of participants

Sub-aim A: Adult participants
A total of 78 adult ears (58 normal hearing; 20 with hearing loss) were evaluated with DPOAEs. A total of 90 adult ears (66 normal hearing ears; 24 ears with hearing loss) were tested using TEOAEs.

Sub-aim B: Infant participants
A total of 176 infants were included in the sample. DPOAE screening was completed in 175 infant ears while TEOAE screening was completed in 174 infant ears.

Main criteria for inclusion

Adults (sub-aim A)

- ≥ 18 years old.
- Adults with normal hearing. Normal hearing is classified as having a pure tone average (PTA) of ≤25 dB HL. PTA is based on the average of an individual's behavioral pure tone air conduction audiometry thresholds obtained at 0.5 kHz, 1 kHz, and 2 kHz.
- Adults with sensorineural hearing loss (SNHL) of any degree (mild, moderate, severe or profound) will also be included in this investigation. SNHL is classified as air conduction PTA of >25 dB HL, and bone conduction thresholds within 10 dB HL of air conduction thresholds across all frequencies.
- Adults who were competent in either English or Afrikaans in order to follow instructions during the assessment procedures.

Infants (sub-aim B)

- Infants younger than 12 months of age, enrolled in the NHS programme at three targeted hospitals, to undergo hearing screening by an audiologist using both the hearOAE and the predicate device.

Criteria for evaluation:

Sub-aim A (Adults)

Primary endpoint criteria for sub-group A (adults) considered both test-retest reliability and validity of the investigational device compared to the predicate device. 95% CI of the test-retest difference of the hearOAE (DPOAE and TEOAE) signal, noise and SNR had to be within a -3.0 to 3.0 dB SPL (lower and upper limit) margin.

Acceptance criteria for validity was when the 95% CI lower limit of the signal difference (DPOAE and TEOAE) between the hearOAE and predicate device was no less -3.0 dB SPL across frequencies.

Sub-aim B (Infants)

The primary endpoint for the infant group was equivalent screening outcomes (device agreement of > 85%) for the investigational device and the comparator device. This was done by measuring device agreement for screening DPOAEs and TEOAEs between the investigation device and the comparator device in terms of Pass/Refer rates, mean signal, noise and SNR. High device agreement was considered > 85%.

Statistical methods

Sub-aim A (Adults)

Test-retest reliability was measured for each device within protocols and within-participant groups (normal and hearing loss). Due to the non-parametric nature of the data, Wilcoxon signed-rank (WSR) tests were used to compare the means of the two OAE devices in terms of Signal, Noise and SNR for both DPOAEs and TEOAEs. Mean absolute deviations were calculated for Signal, Noise and SNR, and is presented for both devices. Non-parametric inferential statistics were used for both DP- and TEOAEs to determine within-participant test-retest reliability within devices.

Sub-aim B (Infants)

Normality of distribution of all dependent variables was evaluated using the Shapiro-Wilk test. Within-participant comparisons were done with the Wilcoxon Sign Rank test. Quantile regression was used to determine if any participant factors were significantly associated with a difference in DPOAE or TEOAE Signal.

Summary – Conclusion

The diagnostic performance of the hearOAE, a novel mobile based OAE device, was evaluated by comparing the DPOAE and TEOAE test-retest reliability and validity of the hearOAE with a commercially available device, namely the ILO288 ECHOPORT Plus OAE System.

Sub-aim A (Adults)

Test-retest reliability of DPOAE and TEOAE

Pooling all independent variables, the hearOAE DPOAE displayed statistically significant (rho = 0.952; $p < 0.001$) test-retest reliability. No significant differences were noted across all frequencies for the DPOAE signals ($p > 0.05$). The 95% confidence limits for signal, noise and SNR differences were within a 3 dB SPL margin across frequencies, aligning well with the predicate device, confirming the hearOAE's DPOAE test-retest reliability.

For TEOAE variables, hearOAE test-retest reliability was statistically significant (rho= 0.965, $p < 0.001$). Frequency specific correlations for signal and SNR were also statistically significant (rho= 0.923-0.985, $p < 0.001$), with no significant differences across frequencies for the TEOAE signal, noise or SNR ($p > 0.05$). The 95% confidence intervals for test-retest differences fell within a 3 dB SPL margin

and mirrored the predicate device, meeting the performance criteria for TEOAE test-retest reliability.

Validity of DPOAE and TEOAE

Initial device comparisons showed that hearOAE DPOAE signals across the frequency bands were either comparable to or significantly better ($p < 0.05$) than the predicate (WSR range: -1.232 to 2.8195). Noise levels were consistently lower for hearOAE (WSR range: -7.323 to -6.197; $p < 0.001$). Excluding the 3 kHz signal, differences between hearOAE and the predicate device were non-significant across all frequencies, with all but 3 kHz meeting OAE signal acceptance criteria (lower 95% CI limit ≥ -3.0). Although the 3kHz frequency was slightly outside the acceptable range (-0.5 dB SPL), hearOAE adhered to the validity criteria for DPOAE.

No significant differences in TEOAE signal were found between devices (WSR = -1.276; $p > 0.05$). hearOAE displayed significantly higher means signals at 3 kHz (WSR=-2.183; $p < 0.029$). Signals were comparable at other frequencies (WSR range: -2.284 to -1.149; $p > 0.05$), with small mean differences (< 1 dB SPL) except at 3 and 4 kHz. All frequencies met the TEOAE signal acceptance criteria (lower 95% CI limit ≥ -3.0), ensuring hearOAE's compliance with the validity acceptance criteria.

Sub-aim B (Infants)

Statistically significant within-participant differences for DPOAEs were measured between devices with respect to both total and mean signal, noise, and SNR levels across frequencies (WSR=-7.901 to -3.004; $p < 0.05$). Signal and SNR values were significantly higher for the predicate, while noise levels were significantly lower for the hearOAE. There was no statistically significant difference in the refer rate between devices (CHI=2.00; $p >0.05$). The within-participant diagnostic concordance between the two devices was 89.7%.

Statistically higher SNR (WSR=-6.664; $p < 0.001$), signal (WSR=-6.199; $p <0.001$), and noise levels (WSR= -2.021 to -2.020; $p = 0.043$) were recorded for the hearOAE compared to the predicate. Within-participant diagnostic concordance of 85% was measured between devices. The refer rate for TEOAEs between devices differed significantly (CHI 7.538; $p = 0.009$) with hearOAE demonstrating a higher pass rate.

Conclusion

The current study concluded that the hearOAE therefore yielded reliable and valid diagnostic DPOAE and TEOAE measures in adults with normal hearing and with hearing loss and demonstrated diagnostic agreement during screening in infants as compared to the predicate device (the IL0288 ECHOPORT Plus OAE System).

9. Substantial Equivalence

The hearOAE has the same intended use as the predicate device Otodynamics ILO288 Plus OAE System (K983350). Like the predicate device, hearOAE is intended to be used by hearing healthcare professionals in the audiologic evaluation and documentation of ear function and ear disorders using Transient Evoked Otoacoustic Emissions (TEOAEs) and Distortion Product Otoacoustic Emissions (DPOAEs). The target population for the hearOAE includes all ages. Clinical data shows that the

effectiveness of the hearOAE was non-inferior to the predicate. Non-clinical performance testing has been conducted to ensure that the device does not raise any concerns or questions of safety and effectiveness as established by the predicate device. The hearOAE software has been validated per the same standards as used to validate the device and software of the predicate device. Lastly, design verification results demonstrate that the subject device has comparable performance to the predicate device.

10. Summary - Conclusion

In conclusion the evidence provided proves that the outcomes of the hearOAE testing have been conducted to ensure that the device does not raise any questions of safety and effectiveness. Furthermore, the hearOAE has the same intended use and the same technological characteristics as the previously cleared predicate device. Based on the comparison and analysis above, the hearOAE is determined to be substantially equivalent to the predicate device (Otodynamics ILO288 Echoport Plus OAE System (K983350)).