March 14, 2023

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

Re: K223137
Trade/Device Name: Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QUH
Dated: February 1, 2023
Received: February 1, 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 (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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223137

Device Name
Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application

Indications for Use *(Describe)*
The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application is a self-fitting air-conduction hearing aid, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The device is adjusted by the user to meet the user's hearing needs. The device is intended for use without the assistance of a hearing care 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

1. SUBMITTER

Name: hearX SA (Pty) Ltd
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Establishment Registration Number: 3014337591
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Phone: +27 12 030 0268
Email: Compliance@hearxgroup.com
Date Prepared: 26 September 2022

2. SUBJECT DEVICE

Name of Device: Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application
Common or Usual Name: Hearing Aid
Classification Name: Self-Fitting, Air-Conduction Hearing Aid, Over the Counter (21 CFR 874.3325)
Regulation Class: Class II
Product Code: QUH
Assigned K-number: K223137

3. PREDICATE DEVICE

Braun® Clear™ Hearing Aid BHA100 Series (K212609)
This predicate device has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

Per 21 CFR 874.3325 a self-fitting wireless air conduction hearing aid is a wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings. Self-fitting wireless air conduction hearing aids are class II medical devices.

Device Characteristics

The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application is a self-fitting, air conduction hearing aid consisting of the IntriCon hardware, Lexie Software, Lexie Application and accessories supplied in the carton. The Lexie App is available on Android and iOS. The Lumen self-fitting OTC hearing aid is the only model applicable to this 510(k).
The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application is a behind the ear device that includes self-adjustable coupling by means of a slim tube and ear tip/dome. The hearing aids can be fine-tuned remotely by trained hearing experts, at the request of the user, in the Lexie contact center. The Lexie app receives custom remote settings as performed through the Lexie adjustment wizard and fitting portal (internet service).

Environment for Use

The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application are to be used in a Home Healthcare Environment. Any environment where personnel with medical training are

not continually available to oversee or administer the use of medical devices. This includes, but is not limited to, outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes.

Brief Description

The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application is designed for a single user. Once the hearing aids are switched on, the software (Lexie app) is required for the initial set-up of the hearing aids. The software can then be used to manage the day-to-day use of the hearing aids. The Lumen is a slim tube style, behind-the-ear, non-rechargeable hearing aid intended to be used for perceived mild to moderate hearing impairment. The hearing aid is intended to be used with the Lexie App and to be worn and removed daily by the end user.

Materials of Use

The hearing aid makes long term/permanent contact with the skin in and around the ear. The body of the hearing aid rests on the outer shell of the ear (behind the ear) and is coupled to a dome via a slim tube that is worn inside of the ear canal. The hearing aid is intended to be used with the Lexie App and to be worn and removed daily by the end user.

The materials used in the construction of the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application are biocompatible presenting no biological risk; thus, the requirements of ISO 10993-1 have been met.

Key Performance Specifications

The hearing aids are used with a replaceable, disposable, 1.45V, size 312 zinc air battery. The digital signal processing on the hearing aids allows for the following features to be adjustable: 16 channel-wide dynamic range compression channels, 16 frequency bands, noise reduction, feedback cancellation, wind noise suppression, low level expansion and microphone arrays (adaptive and fixed microphone directionality).

5. INTENDED USE / INDICATIONS FOR USE

The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application is a self-fitting air-conduction hearing aid, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The device is adjusted by the user to meet the user's hearing needs. The device is intended for use without the assistance of a hearing care professional.

6. LABELING

Self-Selection Labeling has been included in the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application product label and Instructions for Use (IFU) to mitigate the risk of improper self-selection. Summarized, it addresses the following:

- Identifying situations in which the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application may help users hear better;
- Identifying situations in which the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application may not be right for users.
- Identifying criteria that indicate users should see a hearing professional.
- Informing users that the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application will not restore normal hearing.

- Informing users that it is good health practice to have hearing loss evaluated by a licensed healthcare professional.

7. SPECIAL CONTROLS

The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application conforms to the special controls stated in 21 CFR 874.3325.
These requirements are satisfied through following:

- Clinical Performance Validation
- Non-clinical Performance Testing
- Summative Usability/Human Factors Validation
- Labeling

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application has the same intended use and fundamental technology as the predicate, Braun® Clear™ Hearing Aid BHA100 Series (K212609). In the same manner as its predicate, the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application is a user-fitted wireless air-conduction hearing aid intended for over-the-counter use by individuals 18 years or older with perceived mild to moderate hearing impairment.

The same fundamental scientific technology is present in both hearing aids to allow the user to control and customize the device to the user's hearing needs. The subject device is essentially equivalent to the predicate in product design, dimension, use of Bluetooth technology and utilizing materials of high standard. The principles of operation of the subject device is explained as equivalent to the predicate. The subject device has no known bio-compatibility issues, no known effect on the environment, or to other devices.

At a high level, the subject and predicate devices are based on the following technological elements:

- Self-fitting Air Conduction Hearing Aids
- Home Healthcare Environment Use
- Wireless Application via Bluetooth
- On device controls
- App (Lexie Application)
- Software Platform Compatibility (iOS, Android)
- Batteries (Replaceable, disposable, 1.45 Volt, Size 312, Zinc Air, Batteries)
- Behind-The-Ear (BTE)
- Bi-directional Microphones
- User-Adjustable Wire
- Different size ear tips
- Feedback Cancellation
- 16 Channel-wide Dynamic Input Compression
- Open and Closed Ear Tips in 3 sizes (Small, Medium, Large)
- 16 channel Noise Reduction

The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application includes:

- 16 Adjustable Frequency Bands
- Wind Noise Suppression
- Low Level Expansion, Adaptive and Fixed Microphone Directionality

- Wireless User Control Functions via Lexie App

Any differences between the subject and predicate device have been addressed through testing to a known performance standard or by showing equivalence in terms of functioning. These differences are not significant and do not change the effectiveness or safety of the subject device.

9. CLINICAL STUDIES

Study design:

The aim of this study was to compare the outcomes of the Lexie self-fitting strategy (SF) to the same hearing aid fitted by an audiologist (AF). This randomized controlled trial was conducted at the University of Pretoria, located in Gauteng, South Africa. In this study, the SF condition means that participants were provided with the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application and were asked to set up and manage the devices using the Lexie app, entirely without professional support, as would be standard for this OTC model. Hearing aids were provided in their standard, consumer packaging, including all labeling and instructional material. Furthermore, they were fitted according to the proprietary fitting algorithm (Lexie Comfort) using the in-situ thresholds obtained via the Lexie app. The fitting algorithm is based on National Acoustics Laboratories' Non-Linear Version 2 (NAL-NL2), with additional adjustments aimed for a greater listening comfort. In the AF condition, participants were provided with the same Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application fitted to match the National Acoustics Laboratories' Non-Linear Version 2 (NAL-NL2) acoustic gain prescriptions as closely as possible. AF fitting was based on diagnostic audiometry conducted in a soundproof booth by the audiologist. Afterward, the participants in the AF group were orientated on the use and management of the hearing aid by the audiologist. Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application used in the study were identical to the device included for this submission.

The study was conducted as two phases (four visits per participant) of a randomized controlled trial (RCT).

Phase I was a two-week, take-home field trial after fitting the hearing aids. During the first 2-weeks (mean duration = 16 days; SD = 5.8 days) no assistance or fine-tuning by the online Lexie hearing experts for the SF group was allowed, and no fine-tuning by the audiologist in the AF group. This procedure was followed to isolate and only compare the benefit provided by the fitting without the help of online support or adjustment.

Phase II commenced at the first follow-up appointment on the third clinical visit. During this appointment, participants of the AF group were allowed to request fine-tuning or assistance from the audiologist, if desired. The participants in the SF group were informed that assistance could be sought through the Lexie online hearing experts, if desired. Phase II was approximately 6 weeks in duration (mean duration = 40.4 days; SD = 15.9 days), and upon completion the final clinic visit and assessments were conducted. Figure 1 provides an overview of the study protocol. Blinding of the participants and researchers was not possible.

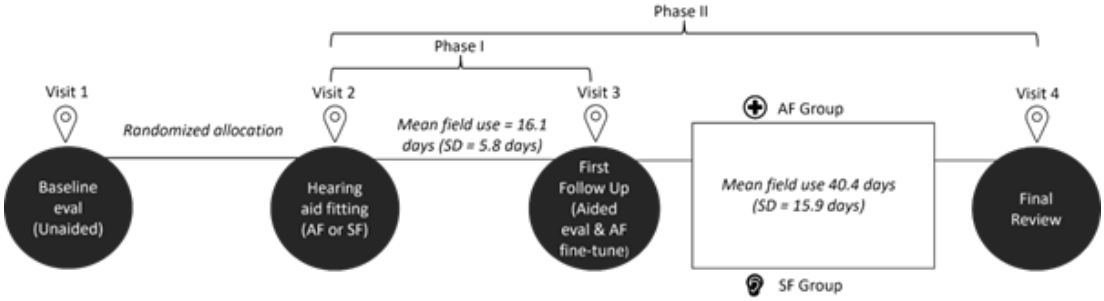


Figure 1. **Trial timeline and design**

The primary endpoint measure of this study was subjective benefit. This was conducted using the Abbreviated Profile of Hearing Aid Benefit (APHAB; primary endpoint variable) and the International Outcome Inventory of Hearing Aids (IOI-HA; secondary endpoint variable). Speech recognition in noise performance measured using the QuickSIN and digits-in-noise test (DIN) (secondary endpoint).

Participant Description

Table 1 below summarizes the participant characteristics for AF and SF groups, respectively. Overall, the analytical sample consisted of 64 participants between the ages of 30 and 84 years (mean = 63.6 years; SD = 14.1 years). Thirty-one were female, with a balanced gender distribution between the two groups. Eighteen participants (27%) had previous experience with a hearing aid, the time of experience ranging between two weeks and 12 years. The self-perceived degree of hearing loss (proportions of *'I have a little trouble*' and '*I have a lot of trouble*') was evenly distributed between the two groups. The distribution of pure tone air-conduction audiometry results (conventional, reference audiometric thresholds), between 0.5 and 6 kHz, are presented in Figure 2. There was no significant difference in age (U = 440, z = -1.34, p = .18), or four frequency pure tone average (PTA 0.5 to 4 kHz), (U = 442, z = -1.3, p = .18) between the two groups.

Table. Summary characteristics of the AF and SF participants

	AF Group	SF Group
Sample size- total	32	32
Gender		
Male (*n*)	18	15
Female (*n*)	14	17
Age		
Mean (SD)	65.3 (14.9)	62.0 (13.1)
Median (IQR)	67 (18)	63 (20)
Race		
White (*n*)	22	27
Black (*n*)	1	2
Asian (*n*)	9	2
Other (*n*)	0	1
HA experience		
New HA users (*n*)	26	21
Experienced HA users (*n*)	6	10
Self-perceived hearing loss		
I have a little trouble (*n*)	20	20
I have a lot of trouble (*n*)	12	12

AF = Audiologist fit; SF= self-fit

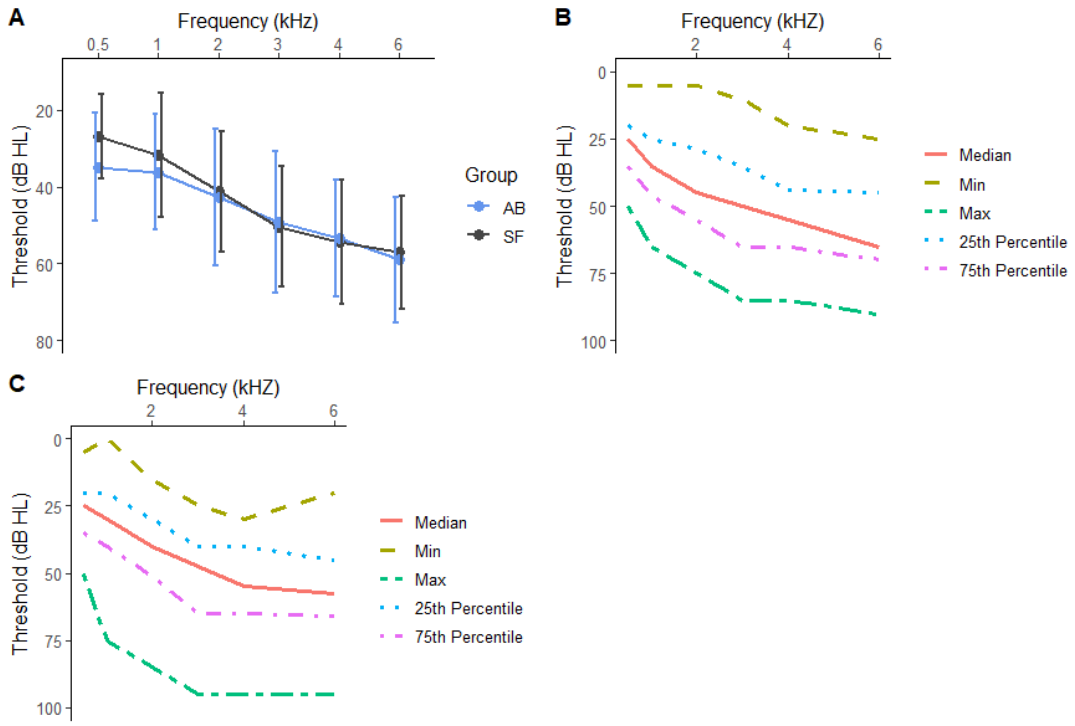


Figure 2. Distribution of conventional pure tone audiometric frequencies combined left and right. (A) Distribution of pure tone thresholds for AF group, (B) Distribution of pure tone thresholds for the SF group. SF= self-fit; AF = audiologist fit, (C) Mean thresholds at 0.5 to 6 kHz, with error bars as standard deviation for the SF and AF groups.

Study Procedures

Visit 1: Baseline assessment

All participants received a standard audiometric evaluation, ensuring that participants met the inclusion criteria set out in the study protocol. This included otoscopy and pure tone air- and bone-conduction audiometry performed by the audiologist. Participants also completed an in-situ hearing test conducted via the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application, connected to the Lexie app in the soundproof booth. This was done by the participants independently.

Results of a separate clinical validation study confirmed the accuracy of the Lumen in-situ hearing check on a sample of 45 participants (90) ears, with varying levels of sensorineural hearing loss between 10 to 75 dB HL. In this study, the mean absolute difference (MAD) between the in-situ hearing test performed independently and the audiologist-performed audiometry varied between 5.8 to 8.1 across 0.5 to 6 kHz (Figure 3). This difference fell within a clinically accepted range of 10 dB HL.

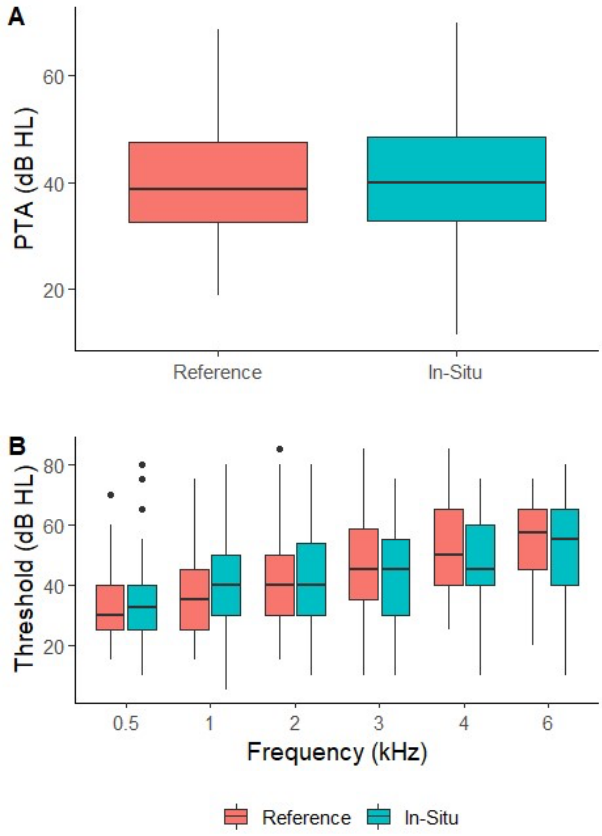


Figure 3. Measured reference versus in-situ audiometry. (A) Reference versus in-situ PTA(0.5 to 4 kHz), (B) Reference versus in-situ thresholds across 0.5 to 6 kHz

Baseline unaided QuickSIN and Digits-in-Noise (DIN) tests were performed. The QuickSIN was developed as a shortened version of the Speech-in-Noise Test (SIN^{TM}) [3], to measure an SNR loss of hearing. In addition to the QuickSIN, speech-in-noise performance was measured using the South African English Digits-in-Noise test (DIN). The Abbreviated Profile of Hearing Aid Benefit (APHAB) was conducted to measure unaided subjective hearing difficulties. T

Visit 2: Hearing-aid fitting

After the clinical research audiologists established candidacy and conducted all baseline measures during Visit 1, participants were booked for Visit 2 for hearing aid fitting. During Visit 2, before fitting, participants were randomly allocated to the SF or AF group using a randomization app.

AF group

The audiologist assisted participants in downloading the Lexie app and signing into their pre-created Lexie profile. The app functionality for the AF group was limited to volume and program controls and without access to the step-by-step onboarding tasks, online hearing experts, or the option to conduct the in-situ test via the app, which was provided to the SF participants. Real-ear measurements were conducted to fit the hearing aids to match the NAL-NL2 prescriptive target within a 5dB tolerance limit.

SF group

Participants in the SF group were provided with the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application in their standard packaging. Participants were then asked to set up the hearing aids through the app or by following the instructions in the user manual. The set-up included the online onboarding tasks, which are text and animated illustrations explaining how to set up and manage the hearing aids as well as an in-situ measurement procedure. The researchers provided no assistance in setting up or managing the hearing aids.

Visit 3: First follow up

After approximately 2 weeks (mean = 16 days; SD = 5.8 days; Figure 2) participants returned for a first follow-up assessment. Aided APHAB was completed along with the International Outcome Inventory for Hearing Aids (IOI-HA). Furthermore, participants completed an aided QuickSIN and DIN test.

After conducting the aided assessment, participants in the AF group were allowed to request fine-tuning or re-orientation by an audiologist, if desired. Participants in the SF group were informed that they could solicit help online by contacting the Lexie call-center. Call-center adjustments included any further hearing aid support by means of remote fine-tuning of the hearing aids, counseling, information, and troubleshooting. Then the participants were sent home, which marked the commencement of Phase II study.

Visit 4: Final Review

After approximately 6 weeks (mean = 40.4 days; SD = 15.9 days; Figure 2) participants returned for their final hearing aid review. Aided APHAB and IOI-HA were completed, and then subsequently proceeded with the aided QuickSIN and DIN. Participants in the SF group were asked whether they contacted the Lexie call center. However, the Lexie product experts also recorded all instances when participants requested assistance (capturing the nature of the problem as well as steps taken to remediate the issue). All SF participants could contact the Lexie call-center anytime between Visit 3 and 4.

Study results

Primary endpoint analysis:

There were no significant differences for unaided baseline scores between the two groups on any subscale or global score. When re-evaluating after a two-week follow-up field trial, the participants in the SF group had less difficulty in background noise ($p < .05$) compared to the AF group. At six-weeks, independent samples t-test showed no significant differences between SF and AF groups for any of the APHAB (unaided, aided and benefit) scores (Figure 3). The aided and benefit scores fell within the 16.3 acceptance criteria for equivalence at the end of the trial.

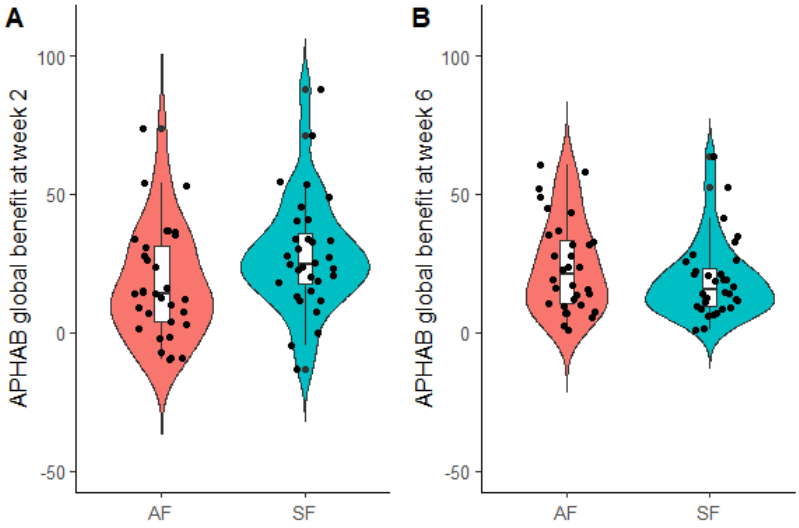


Figure 3. Violin plot with boxplot indicating the distribution of APHAB global benefit scores for the AF and SF group (Positive scores indicate greater benefit). (A) APHAB global benefit scores between AF and SF group at the end of the 2-week trial and (B) APHAB global benefit scores between AF and SF group at the end of the 6-week trial. Violin plots show kernel probability density of thresholds, boxes are interquartile range (with median), and whiskers are 1.5 times the interquartile range. The points show the individual data for each participant in the AF and SF group. *AF indicates audiologist-fit, SF= self-fit.*

Secondary endpoint IOI-HA outcomes:

The IOI-HA was used at the two-week and 6-week field trial points (Figure 4). After the 2-week field trial, participants in the SF group reported a significantly longer duration of hearing aid use per day ($p < .05$). Based on the total score (analyzed using non-parametric statistics as the variables were not normally distributed), there was a significant difference between the two groups, ($p < .05$). However, when re-evaluating at the end of the 6-week trial, the differences between the groups were not significant for any of the subscales or total score ($p > .05$). All the subscales, at two and six-weeks were within the 1-point margin (ordinal scales) of the acceptance criteria. Furthermore, total scores at two and six-weeks fell within the 5-point margin of acceptance criteria.

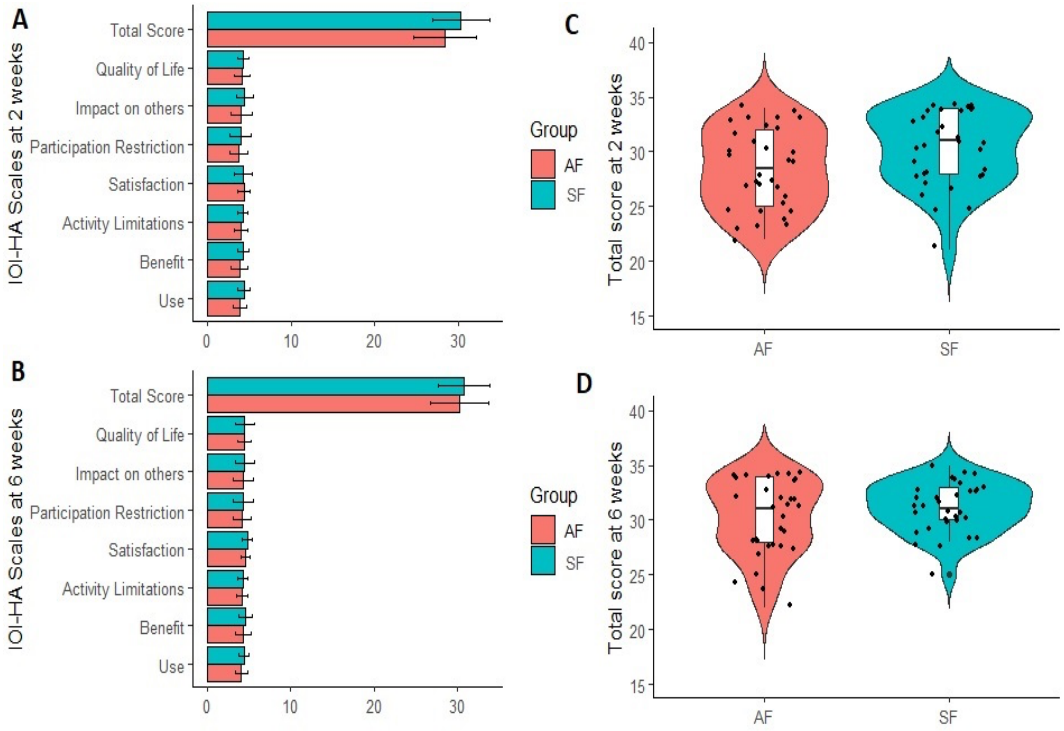


Figure 4. *IOI-HA scores at 2 and 6 weeks for AF and SF groups. (A) Mean IOI-HA scores at 2 weeks across all scales for AF and SF participants (Larger scores indicate larger benefit). Error bars represent 1 SD from the mean. (B) Mean IOI-HA scores at 6 weeks across all scales for AF and SF participants. Error bars represent 1 SD from the mean, (C)Violin plot for the IOI-HA total score for AF and SF groups at 2 weeks showing kernel probability density. Boxes are interquartile range with median, and whiskers are 1.5 times the interquartile range. (D) Violin plot for the IOI-HA total score for AF and SF groups at 6 weeks showing kernel probability density. Boxes are interquartile range with median, and whiskers are 1.5 times the interquartile range.*

Secondary endpoint speech-in-noise outcomes:

At baseline, before hearing aid fitting, there was no significant difference between the groups for either test ($p > .05$). At the end of the 2-week trial, the DIN aided scores were significantly poorer for the AF group than for the SF ($p < .05$), however, within the 1.8 dB SNR acceptance criteria. However, benefit scores were not significantly different between groups for either the QuickSIN or DIN test. When re-evaluated at the end of the 6-week trial, the differences were not significant for either aided QuickSIN or DIN tests ($p > .05$), or the calculated benefit scores.

Effectiveness:

Primary endpoint APHAB outcome: As a primary outcome measure, the SF group was equivalent compared to the AF group at 2-weeks and 6-week post fitting, falling within the marginal acceptance criteria for the APHAB specified for the study.

Secondary endpoint IOI-HA outcomes: The SF group was equivalent compared to the AF group at 2-weeks and 6-weeks post fitting, falling within the marginal acceptance criteria for the IOI-HA specified for the study.

Secondary endpoint speech-in-noise outcomes: The QuickSIN and DIN demonstrated equivalent benefit for the SF compared to AF groups at 2- and 6-weeks post fitting, falling within the marginal acceptance criteria outlined for the study.

The methodology and design of this study was in line with the clinical evaluation of the predicate device BHA 100 Series Braun® Clear™ (subjective and objective performance outcomes) reported in the 510(k) Summary for K212609. The results demonstrate that the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application were non-inferior to fitting by an audiologist using best-practice fitting algorithms. Effectiveness is equivalent to the predicate device (BHA 100 Series Braun® Clear™), which was similarly demonstrated to be equivalent to subjective and objective performance outcomes.

Safety:

The primary endpoint of safety for this clinical study was the occurrence of Adverse Events (AE) and Serious Adverse Events (SAEs). During the course of the study, there was one participant who withdrew from participation two days following hearing aid fitting. The participant developed a middle ear infection, a contraindication for using the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application. A follow-up inquiry by the researcher showed that the event was unrelated to the use of the hearing aid. There were no SAEs occurring for any participant throughout the study. The safety endpoint of the clinical validation study was met. There was only one recorded AE, and after examination, was found to be unrelated to the use of the device. No SAEs were encountered by any of the participants. The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application, therefore, were consistent with the safety profile of the predicate device (BHA 100 Series Braun® Clear™).

a. **Human Factor Testing**

A summative usability / human factors validation test of the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application was conducted in accordance with the following:

- IEC 60601-1-6:2013 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- FDA Guidance - Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff (2016)

This summative human factors evaluation aimed to assess the usability of the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application connected to the Lexie smartphone application (app) when the setup was self-directed by the user. Twenty-nine adult participants were observed during a simulated-use session which assessed the effectiveness and accuracy of the tasks required to set up the hearing aids via the app. Additionally, users' perceptions regarding usability and safety were obtained using a semi-structured interview. The study results indicate that the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application connected to the hearing aid app are usable, as evident by the high success rate (> 79%) on all use-related critical tasks. Two tasks were perceived as challenging while setting up the hearing aids via the app, namely (1) measuring the slim tubes and (2) inserting the hearing aids, indicating an opportunity for improvement in instruction to participants. Even so, only one participant selected the incorrect slim tube size and domes, the implication of which is minimal since it does not pose a risk to safety. Overall, participants displayed a high level of satisfaction when using the hearing aids and app, the majority (65.5%) noting that the hearing aids are “easy to

use" and "user-friendly". The evaluation showed the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application to be safe and effective for intended users and use-environments.

10. NON-CLINICAL PERFORMANCE TESTING:

Non-clinical performance testing was conducted on the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application to provide a reasonable assurance of safety and effectiveness as compared to the predicate device, Braun® Clear™ Hearing Aid BHA100 Series (K212609) and to provide support of substantial equivalence determination to the predicate device. The results are summarized in the table below:

Test Standard/Method	Test Purpose	Result
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 60601-1-11:2015* Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical systems used in the home healthcare environment	Basic Safety and Essential Performance	Pass
IEC 60601-2-66:2019 Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems	Basic Safety and Essential Performance	Pass
IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	Electromagnetic Compatibility	Pass
IEC 60118-13:2019 Electroacoustics – Hearing aids – Part 13: Electromagnetic compatibility	Electromagnetic Compatibility	Pass
ANSI/ASA S3.22:2014 - Specification of Hearing Aid Characteristics	Acoustic Performance	Pass
ANSI CTA 2051:2017 – Personal Sound Amplification Performance Criteria	Acoustic Performance	Pass
ANSI ASA S3.6:2018 - Specification for Audiometers	Audiometric Performance	Pass
IEC 62304:2006+A1:2015 - Medical device software – Software lifecycle processes FDA GuidanceFDA-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
ISO 10993-1:2009/TC 1 2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	Biocompatibility	Pass

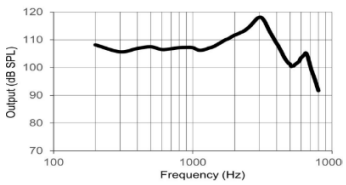
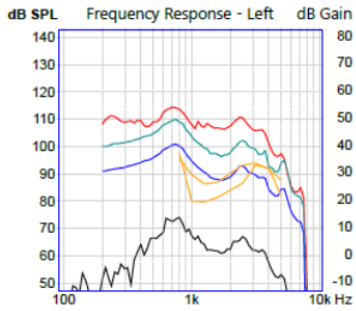
ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. ISO 10993-10:2010 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization ISO 10993-12:2021 - Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials 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		
IEC 60601-1-6:2010+A1:2013 - Medical electrical equipment – Part 1-6:General requirements for basic safety and essential performance - Collateral standard: Usability FDA Guidance FDA-2011-D-0469 - Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff - February 3, 2016	Usability Engineering/Human Factors 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 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	Cybersecurity Compliance	Pass
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
ANSI C63.19:2019 - Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids	Radio Frequency Immunity	Pass

*Applicable sections

Note: Full Non-clinical Performance Testing results, including acceptance criteria and testing performance are reported in the 510(k) submission.

ANSI ASA S3.22:2014 Measurements:

In order to demonstrate substantial equivalence with the predicate device, the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application was evaluated per ANSI ASA S3.22 for acoustic performance. These results are summarized below:

Test	Predicate Device: BHA100 Series Braun® Clear™ hearing aid	Subject Device: Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application	Discussion
OSPL90 Curve			Comparable to Predicate. Performance data support substantial equivalence.
Max OSPL90	Max <120dB SPL Measured 114.4dB SPL	<120dB SPL Measured result 114.4dB SPL	Equivalent to Predicate The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application meets the OTC guidelines for input-controlled compression and a user adjustable volume control that should not exceed an output limit of 117dB SPL at any frequency.
High Frequency Average OSPL90 (HFA-OSPL90)	111 ± 2dB SPL	110dB SPL	Comparable to Predicate. Performance data support substantial equivalence
High Frequency Average Full-on Gain (HFA-FOG)	40 ± 2dB	45dB	Comparable to Predicate. Performance data support substantial equivalence
Reference Test Gain (RTG)	34 ± 4dB	34dB	Equivalent to Predicate
Frequency Response	200Hz to 8000Hz	200Hz to 7000Hz	Comparable to Predicate. Performance data support substantial equivalence The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application meets the OTC guidelines for frequency response where the lower cutoff frequency shall extend to 250Hz or below, and the

			upper cutoff frequency shall extend to 5kHz or greater.
Harmonic Distortion	500 Hz ≤ 1.5% 800 Hz ≤ 2.0% 1600 Hz ≤ 3.0%	< 5% THD@ 500Hz: 0.4% THD@ 800Hz: 0.2% THD@ 1600Hz: 0.4%	Comparable to Predicate. Performance data support substantial equivalence The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application meets the OTC guidelines for harmonic distortion, where the total harmonic distortion plus noise shall not exceed 5 percent for output levels within one of the following sets of levels, depending on the test method.
EIN	<29 dB SPL	<32dB SPL Actual measured value 26.4dB SPL	Comparable to Predicate The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application meets the OTC guidelines for self-generated noise levels where self-generated noise shall not exceed 32 dB SPL. Performance data support substantial equivalence
Latency	<15ms	<15ms	Equivalent to the predicate The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application meets the OTC guidelines for latency, where latency shall not exceed 15ms.

Based on the above information, the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application, and our chosen predicate, BHA100 Series Braun® Clear™ hearing aid (K212609).

11. SUBSTANTIAL EQUIVALENCE

The Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application has the same intended use and as the predicate device, the BHA100 Series Braun® Clear™ hearing aid (K212609). Like the predicate device, the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application is a user-fitted, wireless, air-conduction hearing aid, intended for over-the-counter use by individuals 18 years or older with perceived mild to moderate hearing impairment. Clinical data shows that the effectiveness of the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application was non-inferior to fitting by a licensed audiologist with a calibrated clinical audiometer for both self-fitting hearing assessment/ Furthermore, human

factor testing displayed a high level of user satisfaction and is therefore substantially equivalent to the predicate device in acoustic performance, usability , and safety. Non-clinical performance testing has been conducted to ensure that the device does not raise any questions of safety and effectiveness as established by the predicate device. Device and application firmware and software have been validated per the same standards as used to validate the device and application firmware and software of the predicate device. Lastly, design verification results demonstrate that the subject device has substantially equivalent performance to the predicate device.

12. Summary - Conclusion

The special controls for self-fitting hearing aids as per 21 CFR 874.3325, are met in the following aspects; the clinical data has evaluated the effectiveness of the self-fitting strategy, the electroacoustics parameters (including max output limits, distortion levels, self-generated noise levels, latency, and frequency response) was specified and tested, performance data demonstrates the EMC, electrical and thermal safety of the device. The software verification, validation, and hazard analysis has been performed. The wireless technology performance testing has validated safety of exposure to non-ionizing radiation and validation of wireless technology functions. The usability testing has demonstrated that users can correctly use the device as intended under anticipated conditions of use.

In conclusion the evidence provided proves that the outcomes of the Lexie self-fit model (with Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application) are equivalent to an audiologist's best-practice model. Furthermore, by definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Based on the comparison and analysis above, the Lexie Lumen Self-Fitting OTC Hearing Aid(s) with Lexie Application is determined to be substantially equivalent to the predicate device (BHA 100 Series Braun® Clear™).