April 11, 2024

Sonova AG
Kateryna Konovalenko
Regulatory Affairs Manager
28 Laubisruetistrasse
Staefa, ZH 8712
Switzerland

Re: K232999
Trade/Device Name: Lyric4 Hearing Aid
Regulation Number: 21 CFR 874.3300
Regulation Name: Air-Conduction Hearing Aid
Regulatory Class: Class I
Product Code: ESD
Dated: March 12, 2024
Received: March 12, 2024

Dear Kateryna Konovalenko:

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
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Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

K232999 – 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: April 11, 2024

SUBMITTER:

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DEVICE NAME AND CLASSIFICATION:

TRADE NAME:	Phonak Lyric4
COMMON/USUAL NAME:	Hearing aid
CLASSIFICATION NAMES:	Hearing Aid, Air-Conduction, Prescription
REGULATION NUMBER:	21 C.F.R. § 874.3300
PRODUCT CODE:	ESD
CLASSIFICATION:	Class I
REVIEW PANEL:	Ear, Nose, and Throat

PREDICATE DEVICE

Phonak Lyric4 hearing aid (K130790)

DEVICE DESCRIPTION

Lyric4 is a non-sterile, extended wear hearing aid that is worn 24 hours a day, 7 days a week for months-at-a-time. Due to the deep placement inside the ear canal, it is 100% invisible. For patients, Lyric4 is very easy to operate with no batteries to change, no ongoing maintenance required and no daily insertion or removal. Lyric4 takes advantage of the deep placement in the ear canal for natural sound quality and the natural directivity of the pinna. Lyric4 is designed for single insertion and is not reused once removed from the ear (single-use only).

Compared to the currently marketed Lyric4, there are no modifications to the technology (hardware and software), materials, or accessories when Lyric4 is used for self-replacement. Only the indications for use statement and labeling have been modified. **Figure 1** shows the main components of the Lyric4 device.

1. Insertion handle
2. Microphone protection
3. "This side up" indication
4. Microphone and signal processor
5. Receiver
6. Zinc-air, mercury free battery
7. Medial seal
8. Lateral seal
9. Removal loop
10. *Medial protection seal (for Lyric4 XXS only)

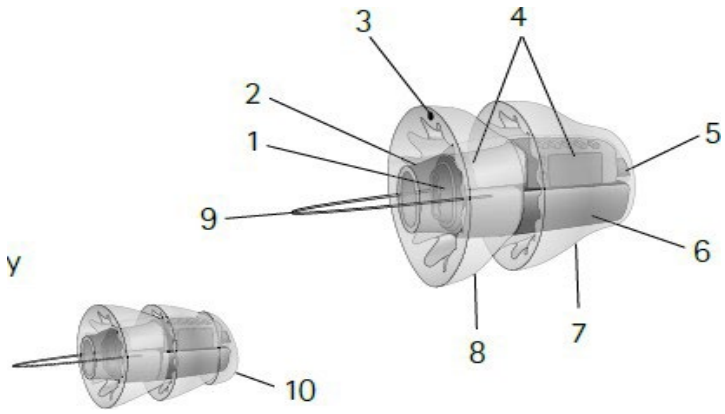

FIGURE 1: LYRIC4 MAIN COMPONENTS

INTENDED USE

The hearing aid is intended to be used to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

INDICATIONS FOR USE

The hearing aid is a disposable, extended-wear air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is initially placed in the ear canal by an appropriately trained ENT physician, Audiologist or Hearing Aid Dispenser and can remain in the ear canal for up to 4 months or until the battery is depleted. It is then replaced by a new device by the previously mentioned parties, or by an adult patient 22 years and older who have been wearing Lyric for a minimum period of 3 months under the direction and training of the ENT physician, Audiologist or Hearing Aid Dispenser. Upon device removal the hearing aid is discarded.

DEVICE COMPARISON

The Lyric4 for self-replacement is substantially equivalent to the following predicate device:

Lyric4 (K130790)

The Lyric4 for self-replacement has the same intended use and technological characteristics compared to the predicate device. The only difference is in the indications for use of the device and the labeling.

Intended Use: Lyric4 (K130790) and Lyric4 for self-replacement are each intended to be used to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

Lyric4 is previously indicated to be fitted and placed in the ear canal by an appropriately trained ENT physician, Audiologist or Hearing Aid Dispenser, and replaced by the previously mentioned parties. Lyric4 for self-replacement extends the indications for use to include replacement by an adult patient under the direction and training of the ENT physician, Audiologist or Hearing Aid Dispenser.

Technological Characteristics: The Lyric4 for self-replacement is identical in technological characteristics to Lyric4, including materials, dimensions, battery capacity and electric circuitry, accessories and the range of sizes offered.

Table 1 and the accompanying discussion below provide a detailed comparison of the intended use of the Lyric4 for self-replacement and the predicate device. As demonstrated below, the intended use of the Lyric4 for self-replacement and the predicate device are the

same. The testing and validation activities described in this 510(k) submission support that Lyric4 for self-replacement is at least as safe and effective as the predicate device.

TABLE 1. COMPARISON OF USE OF THE LYRIC4 FOR SELF-REPLACEMENT AND LYRIC4

	Predicate Device **Sonova AG** **Lyric4** **(K130790)**	**New Device** **Sonova AG** **Lyric4 for self-replacement**	**Discussion**
Manufact./ Name	Phonak LLC	Sonova AG	The legal entity has changed its name from Phonak LLC to Sonova AG
510(k) Number	K130790	This submission	n/a
Product code	ESD	ESD	Same
Classification Regulation	874.3300	874.3300	Same
Indications for Use	The hearing aid is a disposable, extended-wear air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is placed in the ear canal by an appropriately trained ENT physician, Audiologist or Hearing Aid Dispenser and can remain in the ear canal for up to 4 months or until the battery is depleted. Upon device removal the hearing aid is discarded.	The hearing aid is a disposable, extended-wear air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is placed in the ear canal by an appropriately trained ENT physician, Audiologist or Hearing Aid Dispenser and can remain in the ear canal for up to 4 months or until the battery is depleted. It is then replaced by a new device by the previously mentioned parties, or by an adult patient 22 years and older who have	The change to indications for use is subject of this submission. The indications for use of Lyric4 for self-replacement include insertion of a new device by the patient.

	Predicate Device Sonova AG Lyric4 (K130790)	New Device Sonova AG Lyric4 for self-replacement	Discussion
		been wearing Lyric for a minimum period of 3 months under the direction and training of the ENT physician, Audiologist or Hearing Aid Dispenser. Upon device removal the hearing aid is discarded.	
Intended Use	Lyric4 is intended to be used to amplify and transmit sound to the ear and thereby compensate for impaired hearing.	Lyric4 for self-replacement is intended to be used to amplify and transmit sound to the ear and thereby compensate for impaired hearing.	Same
Environment of Use	Home environment	Home environment	Same
Intended User	An adult person requiring sound amplification due to mild or moderately severe hearing loss.	The user of Lyric4 for self-replacement is an adult patient over 22 years of age who have been wearing Lyric for a minimum period of 3 months, requiring sound amplification due to mild or moderately severe hearing loss.	Same. The intended user of the Lyric4 for self-replacement is limited to adult patients over 22 years of age who have been wearing Lyric

	Predicate Device Sonova AG Lyric4 (K130790)	New Device Sonova AG Lyric4 for self-replacement	Discussion
			for a minimum period of 3 months.
Target Anatomic Area	Ear canal, up to the ear drum	Ear canal, up to the ear drum	Same
Type of Patient Contact	Direct contact to the skin for 30 days and longer	Direct contact to the skin for 30 days and longer	Same

As shown in **Table 1**, above, the Lyric4 intended use, or general purpose, is to amplify and transmit sound to the ear and thereby compensate for impaired hearing. This is the same intended use of the Lyric4 for self-replacement. Thus, the Lyric4 for self-replacement and the Lyric4 have the same intended use. The indications for use are subject of the current 510(k) submission.

PERFORMANCE DATA:

Compared to the currently marketed Lyric4, there are no modifications to the technology (hardware and software), materials, or accessories when Lyric4 is used for self-replacement. Only the indications for use statement and labeling have been modified to describe the method for self-replacement. Given there are no differences in device technology, materials, or accessories compared to the legally marketed version of the device, information and testing supporting the shelf-life, biocompatibility, electrical, mechanical, and thermal safety, electromagnetic compatibility, and software are not provided in this 510(k). To support the new indication for user self-replacement, a human factors evaluation and a clinical study were conducted.

a) Non-Clinical Performance Tests

Human factors / Usability tests

Background: Sonova AG performed a summative usability validation (UX) study to assess the effectiveness of the training provided to the HCP to train the end user in the self-replacement process.

Participants: The participants were hearing impaired adults participating in the clinical trial. They were current Lyric4 users and were already wearers of Lyric devices (1 or 2) for at least 3 months to be eligible for SR. A total of 15 participants took part in the summative evaluation. The average age was 59 years and the average time they were already a Lyric user was 2.8 years, ranging from less than 1 year up to 10 years.

Study Design: Summative usability validation took place during Visit 3 of the clinical investigation with a subset of clinical study subjects. The usability sample represented users of various age, sex, and wearers of a range of Lyric4 sizes. The summative usability evaluation was conducted independently from the clinical study. Use-error evaluations included both objective (performance-based) and subjective (user-feedback) evaluations of success for completing the tasks identified as critical for appropriate and safe use. Critical tasks were defined as a use task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care. Study staff captured use-error counts along with responses elicited during follow up questioning to determine root cause.

Results: There were only a few use difficulties and use errors observed. One participant indicated they were aware of having to wash their hands before attempting self-replacement

and would usually perform this task but considered it redundant in the test environment, and thus did not perform the task. Understanding of the atmospheric pressure symbol was the hardest task for all participants. Ten participants required the reference to the instructions for use and managed to find the information they required, while one participant stated they didn't know what that symbol means. This can be taken as evidence that the instructions for use properly support the user when required. No use error or use difficulties were observed that could lead to an unknown potential hazardous situation with unacceptable risk.

b) Clinical Performance Tests

Background: Sonova AG performed the clinical study to demonstrate the effectiveness and safety of the HCP-guided Lyric4 self-replacement procedure, as compared to the commercially available HCP-replacement procedure.

Study Endpoints:

- The primary effectiveness endpoint: Achieved Insertion Depth
- The co-secondary effectiveness endpoints: Aided Audiometric Thresholds and Aided Speech-in-Noise Testing SNR Loss
- The primary safety endpoint: Incidence of Ear Health Issues Requiring Medical Referral and Related to Device Placement
- The secondary safety endpoint: Incidence of Treatment-Emergent Adverse Events
- Exploratory endpoints:
    - Incidence of Gross Placement Errors During Self-Replacement
    - Support Needed Related to Device or Ear Health Concerns
    - Incidence of Persistent, Bothersome Acoustic Feedback at Time of Device Placement

Participants: Fifty-seven experienced Lyric users were enrolled across 8 sites. There were 22 females enrolled in the study and 35 males, and the average age was 63.6 years with a range between 38 and 86 years.

Study Design: This study was a prospective, non-randomized multi-center, longitudinal clinical investigation with a repeated-measures design, in which a single cohort of experienced Lyric4 hearing aid users alternated between HCP-replacement and self-replacement approximately every two weeks over a minimum of 8 and a maximum of 10

pre-scheduled study visits. Due to the anticipated learning effect, the effectiveness endpoints were subjected to hypothesis testing only at the third paired replacement instance. For each study subject, the duration of participation was approximately 14-18 weeks. Unscheduled study visits outside of the pre-determined study visit schedule were incorporated for device issues and ear health management on an as-needed basis. During Visit 3 of the clinical investigation, a summative usability validation (UX) study was conducted with a subset of study subjects. The primary objective of the UX study was to assess the effectiveness of the training provided to the HCP to train the end user in the self-replacement process.

Results:

Primary Effectiveness Endpoint: Achieved Insertion Depth

This measure of effectiveness was an evaluation of the difference between ear-specific achieved insertion depth, measured in mm, in the three paired instances of self-replacement (Data from replacements conducted at visits 3, 5, 7) and HCP-replacement (Data from replacements conducted at visits 1, 4, 6). The Mean Absolute Difference in Achieved Insertion Depth at the 3rd instance was compared to the non-inferiority margin of 2mm to demonstrate non-inferiority of Lyric4 for self-replacement against the HCP-replacement procedure. The Mean Absolute Difference of self-replacement and HCP-replacement has been investigated separately for the left and right ears of the study subjects. There were no major protocol deviations. Results for the Per Protocol (PP) population did not differ significantly from the Intent-to-Test (ITT) population. The ITT data were used for the primary effectiveness analysis as recommended by Section 5.2 of the FDA's "Guidance for Industry E9 Statistical Principles for Clinical Trials" (https://www.fda.gov/media/71336/download).

For purposes of evaluating the statistical non-inferiority of self-replacement compared to HCP-replacement, there is no inherently "good" or "bad" direction to Achieved Insertion Depth. Evaluating Achieved Insertion Depth under the self-replacement condition only makes sense when compared to the companion measurement under the HCP-replacement condition. It does not matter whether Achieved Insertion Depth in the self-replacement is deeper or shallower than Achieved Insertion Depth in the HCP-replacement. It only matters what the magnitude of the absolute difference of each (SELF, HCP) pair is. The Absolute Difference of Achieved Insertion Depth for each (SELF, HCP) pair was the only metric used for confidence intervals and hypothesis testing.

Differences are expressed as the Mean Absolute Difference of SELF-HCP, so a lower Mean Absolute Difference indicates that the achieved insertion depth was, on average, in better agreement between the self-replacement condition and the HCP-replacement condition, whereas a higher Mean Absolute Difference indicates less agreement between the two conditions. The Mean Absolute Difference between the self-replacement condition and the HCP-replacement condition is well below the non-inferiority margin of 2mm. Mean Absolute Differences in Achieved Insertion Depth are shown in **Table 2.**

TABLE 2. MEAN ABSOLUTE DIFFERENCE IN ACHIEVED INSERTION DEPTH, 3RD INSTANCE OF PAIRED-REPLACEMENT (SELF, HCP), ITT POPULATION

Ear	Mean Absolute Difference Achieved Insertion Depth, 3rd Instance	95% Confidence Interval	Non-inferior p-value
Left Ears (N = 50)	0.6 mm	0.30, 0.82 mm	<.0001
Right Ears (N = 49)	0.6 mm	0.35, 0.89 mm	<.0001

Left and right ear groups independently satisfied the acceptance criterion, with the 95% confidence interval of the Mean Absolute Difference less than 2mm, and a p-value of <.0001. Non-inferiority is concluded when comparing the self-replacement procedure to the HCP-replacement procedure, as demonstrated by rejecting the null hypothesis for the primary effectiveness endpoint: Achieved Insertion Depth (mm) in both ears.

Co-Secondary Effectiveness Endpoint: Aided Audiometric Thresholds This measure of effectiveness was an evaluation of the difference between ear-specific aided audiometric thresholds measured at 500, 1000, 2000, and 4000 Hz in the three paired instances of self-replacement (Data from replacements conducted at visits 3, 5, 7) and HCP-replacement (Data from replacements conducted at visits 1, 4, 6). The Estimated Difference in Aided Audiometric Threshold in the 3rd instance was compared to the non-inferiority margin of 10 dB HL to demonstrate non-inferiority of Lyric4 for self-replacement against the HCP-replacement procedure.

The Estimated Difference of self-replacement and HCP-replacement has been investigated separately for the left and right ears of the study subjects. There were no major protocol deviations. Results for the Per Protocol (PP) population did not differ significantly from the Intent-to-Test (ITT) population. The ITT data were used for the primary effectiveness analysis as recommended by Section 5.2 of the FDA's "Guidance for Industry E9 Statistical Principles for Clinical Trials".

Differences are expressed as SELF-HCP, so a negative Estimated Difference indicates that the audiometric threshold was, on average, lower in the self-replacement condition than in the HCP-replacement condition. Estimated Differences between the self-replacement condition and the HCP-replacement condition are well below the non-inferiority margin of 10 dB HL at all 4 frequencies tested. Estimated Differences in Aided Audiometric

Thresholds are shown in **Table 3 and 4 below.**

TABLE 3. THE ESTIMATED DIFFERENCE IN AIDED AUDIOMETRIC THRESHOLDS AT THE 3RD INSTANCE OF REPLACEMENT BETWEEN SELF-REPLACEMENT AND HCP-REPLACEMENT – 50 LEFT EARS

Audiometric Frequency	Estimated Difference	95% Confidence Interval
500 Hz	-0.5 dB HL	-2.39, 1.35 dB HL
1000 Hz	1.5 dB HL	-0.39, 3.31 dB HL
2000 Hz	0.0 dB HL	-2.05, 2.04 dB HL
4000 Hz	1.0 dB HL	-1.77, 3.71 dB HL

TABLE 4. THE ESTIMATED DIFFERENCE IN AIDED AUDIOMETRIC THRESHOLDS AT THE 3RD INSTANCE OF REPLACEMENT BETWEEN SELF-REPLACEMENT AND HCP-REPLACEMENT – 49 RIGHT EARS

Audiometric Frequency	Estimated Difference	95% Confidence Interval
500 Hz	-0.69 dB HL	-2.89, 1.51 dB HL
1000 Hz	0.31 dB HL	-1.66, 2.29 dB HL
2000 Hz	0.89 dB HL	-1.49, 3.27 dB HL
4000 Hz	-0.44 dB HL	-2.46, 1.57 dB HL

Both right and left ear groups independently satisfied the acceptance criterion, with an Estimated Difference of less than 10 dB HL, and a p-value of <.0001 for all four frequencies tested: 500, 1000, 2000, and 4000 Hz. The non-inferiority of Lyric4 for self-replacement has been concluded.

Co-Secondary Effectiveness Endpoint: Aided Speech-in-Noise Testing SNR Loss

This measure of effectiveness was an evaluation of the difference between ear-specific SNR Loss scores measured in the three paired instances of self-replacement (Data from replacements conducted at visits 3, 5, 7) and HCP-replacement (Data from replacements conducted at visits 1, 4, 6). At each testing instance, each subject was administered 2 randomly-chosen QuickSIN lists and a left SNR Loss score and right SNR Loss score was calculated from each list. For both left and right scores, the final Speech-in-Noise Testing SNR Loss score was the average score of the 2 lists. The Estimated Difference in Aided Speech-in-Noise Testing SNR Loss in the 3rd instance was compared to the non-inferiority

margin of 5 dB to demonstrate non-inferiority of Lyric4 for self-replacement against the HCP-replacement procedure.

The Estimated Difference between self-replacement and HCP-replacement has been investigated separately for the left and right ears of the study subjects. There were no major protocol deviations. Results for the Per Protocol (PP) population did not differ significantly from the Intent-to-Test (ITT) population. The ITT data were used for the primary effectiveness analysis as recommended by Section 5.2 of the FDA's "Guidance for Industry E9 Statistical Principles for Clinical Trials".

For the left ears, the upper 95% confidence limit of the Estimated Difference seen in SNR Loss scores between the self-replacement condition and the HCP-replacement condition is below the non-inferiority margin of 5 dB, with a difference between SELF and HCP of 0.10 dB, with a 95% confidence interval ranging from -0.81 dB to 1.01 dB. The adjusted p-value of the non-inferiority test at instance 3 for left ears is below 0.0001 so we conclude non-inferiority.

For the right ears, the upper 95% confidence limit of the Estimated Difference seen in SNR Loss scores between the self-replacement condition and the HCP-replacement condition is below the non-inferiority margin of 5 dB, with a difference between SELF and HCP of 0.46 dB, with a 95% confidence interval ranging from -0.54 dB to 1.46 dB. The adjusted p-value of the non-inferiority test at instance 3 for right ears is below 0.0001, so we conclude non-inferiority.

Both right and left ear groups independently satisfied the acceptance criterion, with a difference of less than 5 dB, and a p-value of <.0001 for the Estimated Difference SNR Loss score of the two QuickSIN lists.

Primary Safety Endpoint: Incidence of Ear Health Issues Requiring Medical Referral and Related to Device Placement

There was one instance of Ear Health Issues Requiring Medical Referral and Related to Device Placement. This issue occurred as a result of cerumen impaction[1], for which the resolution was cerumen management[2].

Secondary Safety Endpoint: Incidence of Treatment Emergent Adverse Events

[1] Cerumen impaction - accumulation of cerumen in the ear canal causing complete or clinically significant occlusion or blockage of the external auditory canal or occurring with clinically relevant symptoms, including pain, itchiness, hearing loss, foul odor, infection, or dermatitis.

[2] Cerumen management - removal of cerumen from the external auditory canal by the utilization of methods and techniques such as irrigation, suction, and manual removal.

Adverse events were attributed to the replacement condition that preceded the onset date of the adverse event. In the case of adverse events that were started under one replacement condition but were not resolved by the time of the other replacement condition, the adverse event was attributed to both conditions.

The overall incidence of AEs was similar when comparing the self-replacement condition and the HCP-replacement condition. A total of 13 (23.21%) subjects experienced Treatment-Emergent Adverse Events attributed to the self-replacement model of care and 17 (29.82%) subjects experienced Treatment-Emergent Adverse Events attributed to the HCP-replacement model of care. A total of 12 (21.43%) subjects experienced Adverse Device Effects attributed to the self-replacement model of care and 16 (28.07%) subjects experienced Adverse Device Effects attributed to the HCP-replacement model of care. One subject (1.79%) withdrew from the study as a result of an Adverse Event under the self-replacement model of care. No subjects experienced Serious Adverse Events or Unanticipated Adverse Device Effects, and no Deaths occurred. When considering overall TEAEs, each subject is represented at most once, and AE severity is classified by the worst severity experienced by a given subject as judged by the HCP. Table 5 shows the incidence of TEAEs classified by event severity and the associated replacement type.

TABLE 5. INCIDENCE OF TREATMENT EMERGENT ADVERSE EVENTS BY REPLACEMENT TYPE AND EVENT SEVERITY

AE Worst Severity Rating by Subject	**N (%)** *Self-Replacement Condition, N = 56*	**N (%)** *HCP-Replacement Condition, N = 57*
Mild	12 (21.43%)	17 (29.82%)
Moderate	0 (0%)	0 (0%)
Severe	1 (1.79%)	0 (0%)

Under both the self-replacement and HCP-replacement models of care, the most common type of TEAE was redness of tissue, occurring in 6 (10.71%) subjects in the Self-replacement condition and in 10 (17.54%) subjects in the HCP-replacement condition. All redness of tissue events were mild. All TEAEs observed under both the self-replacement and the HCP-replacement models of care were commonly observed ear health symptoms in standard Lyric clinical practice. All subjects with reported TEAEs, with the exception of one subject in the Self-replacement condition and one subject in the HCP-replacement condition, experienced device-related AEs.

The second largest category of TEAEs was ‘Other’ (self-replacement condition: 6

(10.71%); HCP-replacement condition: 5 (8.77%)). While this category consisted of AEs unrelated to ear health, the high number of AEs classified under the category 'Other' was primarily a reflection of a limited choice of ear health-related adverse event options that did not include the common symptom of mild discomfort or soreness. While extreme discomfort/soreness was an option, several investigators did not classify reported AEs resulting from discomfort/soreness as extreme. In several cases, the 'Other' option was selected.
Additionally, if a subject reported a symptom at the initial check-in, but the investigator found no underlying cause for the reported symptom, the AE was reported as 'Other.'

AEs that occurred more than once in at least one condition are as follows:

- Blood/bleeding: reported in 1 (1.79%) subject in the self-replacement condition, and in 3 (5.26%) subjects in the HCP-replacement condition.
- Cerumen impaction: reported in 3 (5.36%) subjects in the self-replacement condition, and in 0 (0%) subjects in the HCP-replacement condition.
- Swelling of clotted blood below tissue (bruise): reported in 1 (1.79%) subject in the self-replacement condition, and in 2 (3.51%) subjects in the HCP-replacement condition.

All other AE types, including excess fluid collection on tissue, sore or ulceration of tissue, medial bulge / growth, and sudden drop in hearing occurred at most once under each replacement condition. AEs are mitigated via the Lyric Fitting Guide and HCP training provided to each HCP offering Lyric.

Exploratory Endpoint: Incidence of Gross Placement Errors During Self-Replacement

No instances of gross placement errors were observed during self-replacement.

Exploratory Endpoint: Support Needed Related to Device or Ear Health Concerns

Overall, support contacts for device or ear health concerns were rare in this population, occurring with less than 10% of subjects. During the course of the study, a total of 5 (8.93%) subjects contacted the site for support for device or ear health concerns in the self-replacement condition, and a total of 4 (7.02%) subjects in the HCP-replacement condition. Within these groups of subjects contacting sites for support, the average per-subject number of support contacts made was higher in the self-replacement group, at 1.8 contacts, in contrast with 1.0 contacts in the HCP-replacement group, but this apparent numerical

difference can be attributed to the presence of an outlier in the self-replacement condition who had 4 support contacts. All contacts made under the HCP-replacement condition were device-related, whereas under the self-replacement condition, contacts were made for device issues, ear issues, and issues with the self-replacement process.

Exploratory Endpoint: Incidence of Persistent, Bothersome Acoustic Feedback at Time of Device Replacement

Persistent, bothersome acoustic feedback occurred 5 times in left ears, including a total of 4 times under the self- replacement condition and once under the HCP-Replacement condition. Persistent, bothersome acoustic feedback occurred 4 times in right ears, including a total of twice under each of the replacement conditions (self and HCP). This acoustic feedback at the time of device replacement is mitigated by instructions in the Lyric Fitting Guide directing the users to modify the placement of the Lyric4.

CONCLUSION

The Lyric4 for self-replacement has the same intended use and identical technological characteristics as the predicate device. The differences in the indications for use and labeling do not raise different questions of safety or effectiveness. The clinical performance testing and validation activities described in this 510(k) submission confirm that Lyric4 for self-replacement is substantially equivalent to the predicate device.

K232999 – 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: April 11, 2024

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DEVICE NAME AND CLASSIFICATION:

TRADE NAME:	Phonak Lyric4
COMMON/USUAL NAME:	Hearing aid
CLASSIFICATION NAMES:	Hearing Aid, Air-Conduction, Prescription
REGULATION NUMBER:	21 C.F.R. § 874.3300
PRODUCT CODE:	ESD
CLASSIFICATION:	Class I
REVIEW PANEL:	Ear, Nose, and Throat

PREDICATE DEVICE

Phonak Lyric4 hearing aid (K130790)

DEVICE DESCRIPTION

Lyric4 is a non-sterile, extended wear hearing aid that is worn 24 hours a day, 7 days a week for months-at-a-time. Due to the deep placement inside the ear canal, it is 100% invisible. For patients, Lyric4 is very easy to operate with no batteries to change, no ongoing maintenance required and no daily insertion or removal. Lyric4 takes advantage of the deep placement in the ear canal for natural sound quality and the natural directivity of the pinna. Lyric4 is designed for single insertion and is not reused once removed from the ear (single-use only).

Compared to the currently marketed Lyric4, there are no modifications to the technology (hardware and software), materials, or accessories when Lyric4 is used for self-replacement. Only the indications for use statement and labeling have been modified. **Figure 1** shows the main components of the Lyric4 device.

1. Insertion handle
2. Microphone protection
3. "This side up" indication
4. Microphone and signal processor
5. Receiver
6. Zinc-air, mercury free battery
7. Medial seal
8. Lateral seal
9. Removal loop
10. *Medial protection seal (for Lyric4 XXS only)

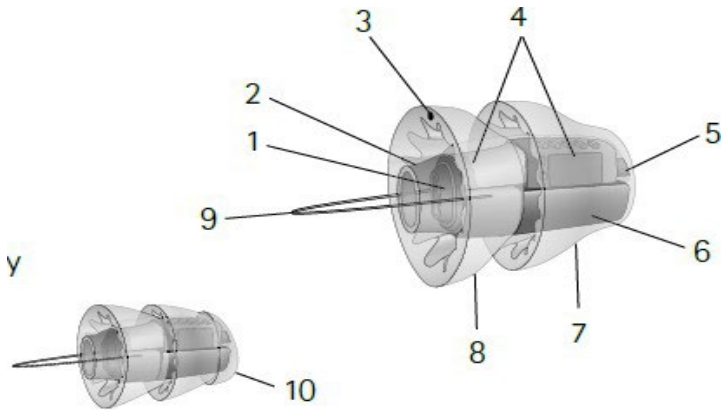

FIGURE 1: LYRIC4 MAIN COMPONENTS

INTENDED USE

The hearing aid is intended to be used to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

INDICATIONS FOR USE

The hearing aid is a disposable, extended-wear air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is initially placed in the ear canal by an appropriately trained ENT physician, Audiologist or Hearing Aid Dispenser and can remain in the ear canal for up to 4 months or until the battery is depleted. It is then replaced by a new device by the previously mentioned parties, or by an adult patient 22 years and older who have been wearing Lyric for a minimum period of 3 months under the direction and training of the ENT physician, Audiologist or Hearing Aid Dispenser. Upon device removal the hearing aid is discarded.

DEVICE COMPARISON

The Lyric4 for self-replacement is substantially equivalent to the following predicate device:

Lyric4 (K130790)

The Lyric4 for self-replacement has the same intended use and technological characteristics compared to the predicate device. The only difference is in the indications for use of the device and the labeling.

Intended Use: Lyric4 (K130790) and Lyric4 for self-replacement are each intended to be used to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

Lyric4 is previously indicated to be fitted and placed in the ear canal by an appropriately trained ENT physician, Audiologist or Hearing Aid Dispenser, and replaced by the previously mentioned parties. Lyric4 for self-replacement extends the indications for use to include replacement by an adult patient under the direction and training of the ENT physician, Audiologist or Hearing Aid Dispenser.

Technological Characteristics: The Lyric4 for self-replacement is identical in technological characteristics to Lyric4, including materials, dimensions, battery capacity and electric circuitry, accessories and the range of sizes offered.

Table 1 and the accompanying discussion below provide a detailed comparison of the intended use of the Lyric4 for self-replacement and the predicate device. As demonstrated below, the intended use of the Lyric4 for self-replacement and the predicate device are the

same. The testing and validation activities described in this 510(k) submission support that Lyric4 for self-replacement is at least as safe and effective as the predicate device.

TABLE 1. COMPARISON OF USE OF THE LYRIC4 FOR SELF-REPLACEMENT AND LYRIC4

	Predicate Device **Sonova AG** **Lyric4** **(K130790)**	**New Device** **Sonova AG** **Lyric4 for self-replacement**	**Discussion**
Manufact./ Name	Phonak LLC	Sonova AG	The legal entity has changed its name from Phonak LLC to Sonova AG
510(k) Number	K130790	This submission	n/a
Product code	ESD	ESD	Same
Classification Regulation	874.3300	874.3300	Same
Indications for Use	The hearing aid is a disposable, extended-wear air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is placed in the ear canal by an appropriately trained ENT physician, Audiologist or Hearing Aid Dispenser and can remain in the ear canal for up to 4 months or until the battery is depleted. Upon device removal the hearing aid is discarded.	The hearing aid is a disposable, extended-wear air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is placed in the ear canal by an appropriately trained ENT physician, Audiologist or Hearing Aid Dispenser and can remain in the ear canal for up to 4 months or until the battery is depleted. It is then replaced by a new device by the previously mentioned parties, or by an adult patient 22 years and older who have	The change to indications for use is subject of this submission. The indications for use of Lyric4 for self-replacement include insertion of a new device by the patient.

	Predicate Device Sonova AG Lyric4 (K130790)	New Device Sonova AG Lyric4 for self-replacement	Discussion
		been wearing Lyric for a minimum period of 3 months under the direction and training of the ENT physician, Audiologist or Hearing Aid Dispenser. Upon device removal the hearing aid is discarded.	
Intended Use	Lyric4 is intended to be used to amplify and transmit sound to the ear and thereby compensate for impaired hearing.	Lyric4 for self-replacement is intended to be used to amplify and transmit sound to the ear and thereby compensate for impaired hearing.	Same
Environment of Use	Home environment	Home environment	Same
Intended User	An adult person requiring sound amplification due to mild or moderately severe hearing loss.	The user of Lyric4 for self-replacement is an adult patient over 22 years of age who have been wearing Lyric for a minimum period of 3 months, requiring sound amplification due to mild or moderately severe hearing loss.	Same. The intended user of the Lyric4 for self-replacement is limited to adult patients over 22 years of age who have been wearing Lyric

	Predicate Device Sonova AG Lyric4 (K130790)	New Device Sonova AG Lyric4 for self-replacement	Discussion
			for a minimum period of 3 months.
Target Anatomic Area	Ear canal, up to the ear drum	Ear canal, up to the ear drum	Same
Type of Patient Contact	Direct contact to the skin for 30 days and longer	Direct contact to the skin for 30 days and longer	Same

As shown in **Table 1**, above, the Lyric4 intended use, or general purpose, is to amplify and transmit sound to the ear and thereby compensate for impaired hearing. This is the same intended use of the Lyric4 for self-replacement. Thus, the Lyric4 for self-replacement and the Lyric4 have the same intended use. The indications for use are subject of the current 510(k) submission.

PERFORMANCE DATA:

Compared to the currently marketed Lyric4, there are no modifications to the technology (hardware and software), materials, or accessories when Lyric4 is used for self-replacement. Only the indications for use statement and labeling have been modified to describe the method for self-replacement. Given there are no differences in device technology, materials, or accessories compared to the legally marketed version of the device, information and testing supporting the shelf-life, biocompatibility, electrical, mechanical, and thermal safety, electromagnetic compatibility, and software are not provided in this 510(k). To support the new indication for user self-replacement, a human factors evaluation and a clinical study were conducted.

a) Non-Clinical Performance Tests

Human factors / Usability tests

Background: Sonova AG performed a summative usability validation (UX) study to assess the effectiveness of the training provided to the HCP to train the end user in the self-replacement process.

Participants: The participants were hearing impaired adults participating in the clinical trial. They were current Lyric4 users and were already wearers of Lyric devices (1 or 2) for at least 3 months to be eligible for SR. A total of 15 participants took part in the summative evaluation. The average age was 59 years and the average time they were already a Lyric user was 2.8 years, ranging from less than 1 year up to 10 years.

Study Design: Summative usability validation took place during Visit 3 of the clinical investigation with a subset of clinical study subjects. The usability sample represented users of various age, sex, and wearers of a range of Lyric4 sizes. The summative usability evaluation was conducted independently from the clinical study. Use-error evaluations included both objective (performance-based) and subjective (user-feedback) evaluations of success for completing the tasks identified as critical for appropriate and safe use. Critical tasks were defined as a use task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care. Study staff captured use-error counts along with responses elicited during follow up questioning to determine root cause.

Results: There were only a few use difficulties and use errors observed. One participant indicated they were aware of having to wash their hands before attempting self-replacement

and would usually perform this task but considered it redundant in the test environment, and thus did not perform the task. Understanding of the atmospheric pressure symbol was the hardest task for all participants. Ten participants required the reference to the instructions for use and managed to find the information they required, while one participant stated they didn't know what that symbol means. This can be taken as evidence that the instructions for use properly support the user when required. No use error or use difficulties were observed that could lead to an unknown potential hazardous situation with unacceptable risk.

b) Clinical Performance Tests

Background: Sonova AG performed the clinical study to demonstrate the effectiveness and safety of the HCP-guided Lyric4 self-replacement procedure, as compared to the commercially available HCP-replacement procedure.

Study Endpoints:

- The primary effectiveness endpoint: Achieved Insertion Depth
- The co-secondary effectiveness endpoints: Aided Audiometric Thresholds and Aided Speech-in-Noise Testing SNR Loss
- The primary safety endpoint: Incidence of Ear Health Issues Requiring Medical Referral and Related to Device Placement
- The secondary safety endpoint: Incidence of Treatment-Emergent Adverse Events
- Exploratory endpoints:
    - Incidence of Gross Placement Errors During Self-Replacement
    - Support Needed Related to Device or Ear Health Concerns
    - Incidence of Persistent, Bothersome Acoustic Feedback at Time of Device Placement

Participants: Fifty-seven experienced Lyric users were enrolled across 8 sites. There were 22 females enrolled in the study and 35 males, and the average age was 63.6 years with a range between 38 and 86 years.

Study Design: This study was a prospective, non-randomized multi-center, longitudinal clinical investigation with a repeated-measures design, in which a single cohort of experienced Lyric4 hearing aid users alternated between HCP-replacement and self-replacement approximately every two weeks over a minimum of 8 and a maximum of 10

pre-scheduled study visits. Due to the anticipated learning effect, the effectiveness endpoints were subjected to hypothesis testing only at the third paired replacement instance. For each study subject, the duration of participation was approximately 14-18 weeks. Unscheduled study visits outside of the pre-determined study visit schedule were incorporated for device issues and ear health management on an as-needed basis. During Visit 3 of the clinical investigation, a summative usability validation (UX) study was conducted with a subset of study subjects. The primary objective of the UX study was to assess the effectiveness of the training provided to the HCP to train the end user in the self-replacement process.

Results:

Primary Effectiveness Endpoint: Achieved Insertion Depth

This measure of effectiveness was an evaluation of the difference between ear-specific achieved insertion depth, measured in mm, in the three paired instances of self-replacement (Data from replacements conducted at visits 3, 5, 7) and HCP-replacement (Data from replacements conducted at visits 1, 4, 6). The Mean Absolute Difference in Achieved Insertion Depth at the 3rd instance was compared to the non-inferiority margin of 2mm to demonstrate non-inferiority of Lyric4 for self-replacement against the HCP-replacement procedure. The Mean Absolute Difference of self-replacement and HCP-replacement has been investigated separately for the left and right ears of the study subjects. There were no major protocol deviations. Results for the Per Protocol (PP) population did not differ significantly from the Intent-to-Test (ITT) population. The ITT data were used for the primary effectiveness analysis as recommended by Section 5.2 of the FDA's "Guidance for Industry E9 Statistical Principles for Clinical Trials" (https://www.fda.gov/media/71336/download).

For purposes of evaluating the statistical non-inferiority of self-replacement compared to HCP-replacement, there is no inherently "good" or "bad" direction to Achieved Insertion Depth. Evaluating Achieved Insertion Depth under the self-replacement condition only makes sense when compared to the companion measurement under the HCP-replacement condition. It does not matter whether Achieved Insertion Depth in the self-replacement is deeper or shallower than Achieved Insertion Depth in the HCP-replacement. It only matters what the magnitude of the absolute difference of each (SELF, HCP) pair is. The Absolute Difference of Achieved Insertion Depth for each (SELF, HCP) pair was the only metric used for confidence intervals and hypothesis testing.

Differences are expressed as the Mean Absolute Difference of SELF-HCP, so a lower Mean Absolute Difference indicates that the achieved insertion depth was, on average, in better agreement between the self-replacement condition and the HCP-replacement condition, whereas a higher Mean Absolute Difference indicates less agreement between the two conditions. The Mean Absolute Difference between the self-replacement condition and the HCP-replacement condition is well below the non-inferiority margin of 2mm. Mean Absolute Differences in Achieved Insertion Depth are shown in **Table 2.**

TABLE 2. MEAN ABSOLUTE DIFFERENCE IN ACHIEVED INSERTION DEPTH, 3RD INSTANCE OF PAIRED-REPLACEMENT (SELF, HCP), ITT POPULATION

Ear	Mean Absolute Difference Achieved Insertion Depth, 3rd Instance	95% Confidence Interval	Non-inferior p-value
Left Ears (N = 50)	0.6 mm	0.30, 0.82 mm	<.0001
Right Ears (N = 49)	0.6 mm	0.35, 0.89 mm	<.0001

Left and right ear groups independently satisfied the acceptance criterion, with the 95% confidence interval of the Mean Absolute Difference less than 2mm, and a p-value of <.0001. Non-inferiority is concluded when comparing the self-replacement procedure to the HCP-replacement procedure, as demonstrated by rejecting the null hypothesis for the primary effectiveness endpoint: Achieved Insertion Depth (mm) in both ears.

Co-Secondary Effectiveness Endpoint: Aided Audiometric Thresholds This measure of effectiveness was an evaluation of the difference between ear-specific aided audiometric thresholds measured at 500, 1000, 2000, and 4000 Hz in the three paired instances of self-replacement (Data from replacements conducted at visits 3, 5, 7) and HCP-replacement (Data from replacements conducted at visits 1, 4, 6). The Estimated Difference in Aided Audiometric Threshold in the 3rd instance was compared to the non-inferiority margin of 10 dB HL to demonstrate non-inferiority of Lyric4 for self-replacement against the HCP-replacement procedure.

The Estimated Difference of self-replacement and HCP-replacement has been investigated separately for the left and right ears of the study subjects. There were no major protocol deviations. Results for the Per Protocol (PP) population did not differ significantly from the Intent-to-Test (ITT) population. The ITT data were used for the primary effectiveness analysis as recommended by Section 5.2 of the FDA's "Guidance for Industry E9 Statistical Principles for Clinical Trials".

Differences are expressed as SELF-HCP, so a negative Estimated Difference indicates that the audiometric threshold was, on average, lower in the self-replacement condition than in the HCP-replacement condition. Estimated Differences between the self-replacement condition and the HCP-replacement condition are well below the non-inferiority margin of 10 dB HL at all 4 frequencies tested. Estimated Differences in Aided Audiometric

Thresholds are shown in **Table 3 and 4 below.**

TABLE 3. THE ESTIMATED DIFFERENCE IN AIDED AUDIOMETRIC THRESHOLDS AT THE 3RD INSTANCE OF REPLACEMENT BETWEEN SELF-REPLACEMENT AND HCP-REPLACEMENT – 50 LEFT EARS

Audiometric Frequency	Estimated Difference	95% Confidence Interval
500 Hz	-0.5 dB HL	-2.39, 1.35 dB HL
1000 Hz	1.5 dB HL	-0.39, 3.31 dB HL
2000 Hz	0.0 dB HL	-2.05, 2.04 dB HL
4000 Hz	1.0 dB HL	-1.77, 3.71 dB HL

TABLE 4. THE ESTIMATED DIFFERENCE IN AIDED AUDIOMETRIC THRESHOLDS AT THE 3RD INSTANCE OF REPLACEMENT BETWEEN SELF-REPLACEMENT AND HCP-REPLACEMENT – 49 RIGHT EARS

Audiometric Frequency	Estimated Difference	95% Confidence Interval
500 Hz	-0.69 dB HL	-2.89, 1.51 dB HL
1000 Hz	0.31 dB HL	-1.66, 2.29 dB HL
2000 Hz	0.89 dB HL	-1.49, 3.27 dB HL
4000 Hz	-0.44 dB HL	-2.46, 1.57 dB HL

Both right and left ear groups independently satisfied the acceptance criterion, with an Estimated Difference of less than 10 dB HL, and a p-value of <.0001 for all four frequencies tested: 500, 1000, 2000, and 4000 Hz. The non-inferiority of Lyric4 for self-replacement has been concluded.

Co-Secondary Effectiveness Endpoint: Aided Speech-in-Noise Testing SNR Loss

This measure of effectiveness was an evaluation of the difference between ear-specific SNR Loss scores measured in the three paired instances of self-replacement (Data from replacements conducted at visits 3, 5, 7) and HCP-replacement (Data from replacements conducted at visits 1, 4, 6). At each testing instance, each subject was administered 2 randomly-chosen QuickSIN lists and a left SNR Loss score and right SNR Loss score was calculated from each list. For both left and right scores, the final Speech-in-Noise Testing SNR Loss score was the average score of the 2 lists. The Estimated Difference in Aided Speech-in-Noise Testing SNR Loss in the 3rd instance was compared to the non-inferiority

margin of 5 dB to demonstrate non-inferiority of Lyric4 for self-replacement against the HCP-replacement procedure.

The Estimated Difference between self-replacement and HCP-replacement has been investigated separately for the left and right ears of the study subjects. There were no major protocol deviations. Results for the Per Protocol (PP) population did not differ significantly from the Intent-to-Test (ITT) population. The ITT data were used for the primary effectiveness analysis as recommended by Section 5.2 of the FDA's "Guidance for Industry E9 Statistical Principles for Clinical Trials".

For the left ears, the upper 95% confidence limit of the Estimated Difference seen in SNR Loss scores between the self-replacement condition and the HCP-replacement condition is below the non-inferiority margin of 5 dB, with a difference between SELF and HCP of 0.10 dB, with a 95% confidence interval ranging from -0.81 dB to 1.01 dB. The adjusted p-value of the non-inferiority test at instance 3 for left ears is below 0.0001 so we conclude non-inferiority.

For the right ears, the upper 95% confidence limit of the Estimated Difference seen in SNR Loss scores between the self-replacement condition and the HCP-replacement condition is below the non-inferiority margin of 5 dB, with a difference between SELF and HCP of 0.46 dB, with a 95% confidence interval ranging from -0.54 dB to 1.46 dB. The adjusted p-value of the non-inferiority test at instance 3 for right ears is below 0.0001, so we conclude non-inferiority.

Both right and left ear groups independently satisfied the acceptance criterion, with a difference of less than 5 dB, and a p-value of <.0001 for the Estimated Difference SNR Loss score of the two QuickSIN lists.

Primary Safety Endpoint: Incidence of Ear Health Issues Requiring Medical Referral and Related to Device Placement

There was one instance of Ear Health Issues Requiring Medical Referral and Related to Device Placement. This issue occurred as a result of cerumen impaction[1], for which the resolution was cerumen management[2].

Secondary Safety Endpoint: Incidence of Treatment Emergent Adverse Events

[1] Cerumen impaction - accumulation of cerumen in the ear canal causing complete or clinically significant occlusion or blockage of the external auditory canal or occurring with clinically relevant symptoms, including pain, itchiness, hearing loss, foul odor, infection, or dermatitis.

[2] Cerumen management - removal of cerumen from the external auditory canal by the utilization of methods and techniques such as irrigation, suction, and manual removal.

Adverse events were attributed to the replacement condition that preceded the onset date of the adverse event. In the case of adverse events that were started under one replacement condition but were not resolved by the time of the other replacement condition, the adverse event was attributed to both conditions.

The overall incidence of AEs was similar when comparing the self-replacement condition and the HCP-replacement condition. A total of 13 (23.21%) subjects experienced Treatment-Emergent Adverse Events attributed to the self-replacement model of care and 17 (29.82%) subjects experienced Treatment-Emergent Adverse Events attributed to the HCP-replacement model of care. A total of 12 (21.43%) subjects experienced Adverse Device Effects attributed to the self-replacement model of care and 16 (28.07%) subjects experienced Adverse Device Effects attributed to the HCP-replacement model of care. One subject (1.79%) withdrew from the study as a result of an Adverse Event under the self-replacement model of care. No subjects experienced Serious Adverse Events or Unanticipated Adverse Device Effects, and no Deaths occurred. When considering overall TEAEs, each subject is represented at most once, and AE severity is classified by the worst severity experienced by a given subject as judged by the HCP. Table 5 shows the incidence of TEAEs classified by event severity and the associated replacement type.

TABLE 5. INCIDENCE OF TREATMENT EMERGENT ADVERSE EVENTS BY REPLACEMENT TYPE AND EVENT SEVERITY

AE Worst Severity Rating by Subject	**N (%)** *Self-Replacement Condition, N = 56*	**N (%)** *HCP-Replacement Condition, N = 57*
Mild	12 (21.43%)	17 (29.82%)
Moderate	0 (0%)	0 (0%)
Severe	1 (1.79%)	0 (0%)

Under both the self-replacement and HCP-replacement models of care, the most common type of TEAE was redness of tissue, occurring in 6 (10.71%) subjects in the Self-replacement condition and in 10 (17.54%) subjects in the HCP-replacement condition. All redness of tissue events were mild. All TEAEs observed under both the self-replacement and the HCP-replacement models of care were commonly observed ear health symptoms in standard Lyric clinical practice. All subjects with reported TEAEs, with the exception of one subject in the Self-replacement condition and one subject in the HCP-replacement condition, experienced device-related AEs.

The second largest category of TEAEs was ‘Other’ (self-replacement condition: 6

(10.71%); HCP-replacement condition: 5 (8.77%)). While this category consisted of AEs unrelated to ear health, the high number of AEs classified under the category 'Other' was primarily a reflection of a limited choice of ear health-related adverse event options that did not include the common symptom of mild discomfort or soreness. While extreme discomfort/soreness was an option, several investigators did not classify reported AEs resulting from discomfort/soreness as extreme. In several cases, the 'Other' option was selected.
Additionally, if a subject reported a symptom at the initial check-in, but the investigator found no underlying cause for the reported symptom, the AE was reported as 'Other.'

AEs that occurred more than once in at least one condition are as follows:

- Blood/bleeding: reported in 1 (1.79%) subject in the self-replacement condition, and in 3 (5.26%) subjects in the HCP-replacement condition.
- Cerumen impaction: reported in 3 (5.36%) subjects in the self-replacement condition, and in 0 (0%) subjects in the HCP-replacement condition.
- Swelling of clotted blood below tissue (bruise): reported in 1 (1.79%) subject in the self-replacement condition, and in 2 (3.51%) subjects in the HCP-replacement condition.

All other AE types, including excess fluid collection on tissue, sore or ulceration of tissue, medial bulge / growth, and sudden drop in hearing occurred at most once under each replacement condition. AEs are mitigated via the Lyric Fitting Guide and HCP training provided to each HCP offering Lyric.

Exploratory Endpoint: Incidence of Gross Placement Errors During Self-Replacement

No instances of gross placement errors were observed during self-replacement.

Exploratory Endpoint: Support Needed Related to Device or Ear Health Concerns

Overall, support contacts for device or ear health concerns were rare in this population, occurring with less than 10% of subjects. During the course of the study, a total of 5 (8.93%) subjects contacted the site for support for device or ear health concerns in the self-replacement condition, and a total of 4 (7.02%) subjects in the HCP-replacement condition. Within these groups of subjects contacting sites for support, the average per-subject number of support contacts made was higher in the self-replacement group, at 1.8 contacts, in contrast with 1.0 contacts in the HCP-replacement group, but this apparent numerical

difference can be attributed to the presence of an outlier in the self-replacement condition who had 4 support contacts. All contacts made under the HCP-replacement condition were device-related, whereas under the self-replacement condition, contacts were made for device issues, ear issues, and issues with the self-replacement process.

Exploratory Endpoint: Incidence of Persistent, Bothersome Acoustic Feedback at Time of Device Replacement

Persistent, bothersome acoustic feedback occurred 5 times in left ears, including a total of 4 times under the self- replacement condition and once under the HCP-Replacement condition. Persistent, bothersome acoustic feedback occurred 4 times in right ears, including a total of twice under each of the replacement conditions (self and HCP). This acoustic feedback at the time of device replacement is mitigated by instructions in the Lyric Fitting Guide directing the users to modify the placement of the Lyric4.

CONCLUSION

The Lyric4 for self-replacement has the same intended use and identical technological characteristics as the predicate device. The differences in the indications for use and labeling do not raise different questions of safety or effectiveness. The clinical performance testing and validation activities described in this 510(k) submission confirm that Lyric4 for self-replacement is substantially equivalent to the predicate device.