March 15, 2024

Concha Labs
℅ Joseph Burke
Regulatory Consultant for Concha Labs
Joseph Burke Consulting Inc.
16 Rebekah Lane
Sutton, Massachusetts 01590

Re: K233747
Trade/Device Name: Concha Sol Hearing Aids (CL-1001)
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QUH
Dated: February 12, 2024
Received: February 12, 2024

Dear Joseph Burke:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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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.

Submission Number *(if known)*

K233747

Device Name

Concha Sol Hearing Aids (CL-1001)

Indications for Use *(Describe)*

The Concha Sol Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. 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.

510(k)#: K233747 **510(k) Summary** **Prepared 12 Feb 2024**

1. CONTACT DETAILS 21 CFR 807.92 (a)(1)

Concha Labs
55 East 3rd Avenue
San Mateo, CA, 94401
Company Contact: Carlos Bullock
Official Correspondent: Joseph Burke

2. DEVICE NAME 21 CFR 807.92 (a)(2)

Name of Device: Concha Sol OTC Hearing Aids (CL-1001)
Common Name: Self-fitting OTC Hearing Aid
Classification Name: Self-fitting Air Conduction Hearing Aid
Regulation: 21 CFR §874.3325
Regulatory Class: II
Product Code: QUH
Review Panel: Ear, Nose and Throat Devices
Use: Over-the-Counter (OTC)

3. LEGALLY MARKETED PREDICATE DEVICE 21 CFR 807.92 (a)(3)

Predicate #: K211008
Predicate Trade Name: Bose SoundControl Hearing Aids
Product Code: QDD

4. DEVICE DESCRIPTION SUMMARY 21 CFR 807.92 (a)(4)

The Concha Sol OTC Hearing Aids (Model CL-1001) are receiver-in-the ear, self-fitting, wireless air conduction hearing aids (§ 874.3325) intended to amplify sounds in the environment for adult users who have a perceived mild-to-moderate hearing loss. The hearing aids include Ear Tips, Carry Case and the Concha Labs mobile application. The device is indicated for over-the-counter sale (product code QUH) and integrates user input with a self-fitting strategy, enabling users to independently derive and customize their hearing aid fitting and settings. Self-fitting wireless air-conduction hearing aids are Class II medical devices. The Self-Fitting hearing aids incorporate microphones for audio input, and sound is delivered to the ear via a receiver that can be coupled with domes.

The mobile application contains a self-fitting software known as Soundscope, an innovative software that uses the NAL-NL2 programming formula used globally by hearing aid manufacturers. The hearing profile/personalization system in the Concha Sol Hearing Aid assesses the individual's hearing levels across a frequency spectrum in order to generate and customize the device's amplification specific to their hearing needs. The self-fitting software also assesses the individual's hearing preferences to help fine-tune the device's amplification. In addition to hearing aid functionality for environmental and directive listening; the hearing aids can also be used for telephony and streaming audio from a Bluetooth® compliant mobile device. The hearing aids are powered using Zinc Air size 312 cell batteries.

5. INTENDED USE 21 CFR 807.92 (a)(5)

The Concha Sol Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for use without the assistance of a hearing care professional.

6. INDICATIONS FOR USE COMPARISON 21 CFR 807.92 (a)(5)

The indications for use of the subject device are "The Concha Sol Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for use without the assistance of a hearing care professional."
A comparison of the indications for use of the Concha Sol Hearing Aids are similar to those of the predicate device (Bose SoundControl Hearing Aid (K211008)); with the exception of the point of sale. The Bose SoundControl is described as a Direct to Consumer (DTC) device (Product code QDD); whereas the Concha Sol Hearing Aids are indicated for Over the Counter (OTC) sale (Product code QUH). The Concha Sol is also in compliance with all elements of the OTC Hearing Aid Final Rule, as well as compliant with OTC requirements for labeling.

7. TECHNOLOGICAL COMPARISON 21 CFR 807.92 (a)(6)

The technological characteristics of the Concha Sol Hearing Aids are similar to those of the predicate device Bose SoundControl Hearing AID (K211008). The table below provides a comparison of the subject and predicate devices. A thorough review of these products revealed the devices are equivalent from a technological perspective.

	Subject Device	Predicate	Discussion
Device Trade Name	**Concha Sol Hearing Aids**	**Bose SoundControl Hearing Aid**	
510k Number	K233747	K211008	
Product code	QUH	QDD	Similar to the predicate with exception of the point of sale: OTC (Concha) vs. DTC (Bose). Subject device complies with OTC hearing aid requirements outlined in 21 CFR 800.30.
Regulation number	21 CFR 874.3325	21 CFR 874.3325	Same as predicate
Regulation name	Self-fitting air conduction hearing aid	Self-fitting air conduction hearing aid	Same as predicate
Intended Use	The Concha Sol Hearing Aid is intended to amplify sound for individuals with perceived mild to moderate hearing impairment.	The Bose SoundControl Hearing Aid is intended to amplify sound for individuals with perceived mild to moderate hearing impairment.	Same as predicate

Indications for Use	The Concha Sol Hearing Aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for use without the assistance of a hearing care professional.	The Bose SoundControl Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.	The subject device has similar Indications for Use as the predicate device ,with the appropriate adjustment in accordance with the OTC Hearing Aid Final Rule.
Battery	Single use 312 Zinc Air Batteries	Single use 312 Zinc Air Batteries	Same as predicate

	Subject Device	**Primary Predicate**	**Discussion**
Device Trade Name	**Concha Sol OTC Hearing Aids**	**Bose SoundControl Hearing Aid**	
Housing	Behind The Ear (BTE) Receiver In Canal (RIC) hearing aid housing. Separate left and right ear units with a separate Ear Tip for each unit. On the device, 'Rocker Switch' used to control volume. Mobile device streaming and phone audio via Bluetooth.	Behind The Ear (BTE) Receiver In Canal (RIC) hearing aid housing. Separate left and right ear units with a separate Ear Tip for each unit. On device, 'Rocker Switch' used to control volume.	Devices are similar with only slight dimensional differences.
Input signal compression	Wide dynamic range compression	Wide dynamic range compression	Same as predicate
Microphones	Microphones may, during use, be configured by the user in omni-directional or directional modes	Microphones may, during use, be configured by the user in omni-directional or directional modes	Same as predicate
Battery Lifetime	Per CTA 2051 (4.1-4.17) Battery life of 5 days, 13 hours per day	Per CTA 2051 (4.1-4.7) Battery life of 4 days, 14 hours per day	The battery life is similar to that of the predicate and differences raise no new questions of safety and effectiveness.

	Subject Device	Primary Predicate	Discussion / Results
Device Trade Name	**Concha Sol OTC Hearing Aids**	**Bose SoundControl Hearing Aid**	
Self-fitting method	Subject device uses a proprietary Soundscope technology, with initial gain parameters based on NAL- NL2.	Loudness and Fine-tuning app-based Controllers. Utilizes a proprietary fitting method.	Performance testing evaluated these differences in technology and the results support substantial equivalence.
Mobile App	Mobile application on a smart device (phone or tablet) with an iOS operating platform.	Mobile application on a smart device (phone or tablet) with either iOS or Android platforms.	Similar to predicate but currently subject device only uses iOS operating platform. This does not raise new issues regarding safety and effectiveness.
Streaming / Telephony	Subject device provides audio streaming and telephone via Bluetooth.	N/A	Predicate does not include the features. They do not raise new issues of safety or effectiveness Performance testing evaluated the differences in technology and the support substantial equivalence.

Electro-Acoustic Characteristics	Subject Device	Primary Predicate	Discussion
	Concha Sol OTC Hearing Aids	**Bose SoundControl Hearing Aid**	**Compliance to §800.30**
Latency Clause	6.7 ms	Less than or equal to 15 ms	Both devices meet requirements
Frequency response	<200Hz - >10000 Hz	<200Hz –> 8000 Hz	Both devices meet requirements
Input Distortion Clause	1.20%	5%	Both devices meet requirements
Equivalent Input Noise (EIN)	18.6 dB SPL	< 27 dB SPL	Both devices meet requirements
Harmonic Distortion	Less than or equal to 1%	Less than or equal to 1%	Same as predicate and meet requirements
Max OSPL90	115.2 dB SPL	113 dB SPL	Both devices meet requirements
HFA OSPL90	113 dB SPL	106 dB SPL	Both devices are adequate for fitting mild to moderate hearing loss as prescribed by NAL- NL2.

HFA FOG	48.4 dB	30 dB	Subject device will provide more high-frequency average full-on gain (HFA-FOG) and therefore more amplification for soft sound inputs. No specific gain limit was identified or required in the Final OTC Hearing Aid rule. Although this value is higher than the predicate Bose SoundControl device by 18.4 dB, the subject device features output limiting (WDRC).
RTG	36.3 dB	29 dB	The subject device is adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. The data from a clinical validation study supports the substantial equivalence between the subject device and the predicate.

These findings, along with the results of performance testing, indicate that the Concha Sol Hearings Aids are substantially equivalent to the Bose SoundControl (K211008) from a technological perspective.

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8. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS 21 CFR 807.92 (b)

Biocompatibility

Compliance to the testing requirements for a limited duration (less than 24 hrs.), direct skin contact device was based on the FDA recognized consensus standards ISO 10993-1 and FDA guidance on application of said standard to medical devices for U.S. market. ISO 10993-1: Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing within a Risk Management Process and FDAs 2020 final guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Biocompatibility assessment outcomes were deemed adequate based on intended use.

Shelf Life/Sterility

The non-sterile hearing aid is maintained by the user by wiping with a dry, soft cloth on the outside surface of the housing; a provided brush assists in removal of visible debris from vents and ear tip. Device is intended to have a 2 year service life while none of the device components are subject to degradation that could impact an ‘endpoint’ of shelf-life.

Electrical Safety:

The Concha Sol Hearing Aid electrical circuitry was tested extensively to verify design criteria and performance with respect to electrical system specifications and properties in support of its safety and effectiveness (IEC 60601-1:2012). The Concha Sol Hearing Aid was tested in finished form and passed testing for battery life, and runtime (ANSI S3.22:2014).

60601

The Concha Sol Hearing Aid was tested per the requirements of IEC 60601-1:2012, standard for medical electrical equipment: General requirements on basic safety and essential performance to provide reasonable assurance of the basic safety and essential performance of the device.

The Concha Sol Hearing Aid was also tested per the requirements of IEC 60601-2-66:2019, standard for medical electrical equipment: Practical requirements for basic safety and essential performance of Hearing Instruments and Hearing Instrument Systems to provide reasonable assurance of the basic safety and performance of the device.

EMC and Wireless

The Concha Sol Hearing Aid was tested per the requirements of IEC 60601-1-2, 2014, AMD1:2020 standard for medical electrical equipment: General requirements on basic safety and essential performance on Electromagnetic Compatibility to provide reasonable assurance that the device performs all/remain functions that are within its specified range of operation in concert with its intended use.

Electroacoustic Testing

The Concha Sol Hearing Aid electroacoustic design was tested extensively to verify design criteria and performance with respect to electroacoustic system specifications and properties in support of its safety and effectiveness. The Concha Sol Hearing Aid passed the following tests not limited to: Monaural/Binaural Directions, Battery Life, and ANSI S3.22/ASA S3.22-2014 and CTA 2051 related tests. Electro Acoustic Measurement Verification was completed and found in compliance with §800.30 requirements and similar to the predicate.

Battery Life Verification

Testing demonstrated that Concha Sol Hearing Aid device meets ANSIS3.22/CTA 2051 standard for manufacturer to report the estimated battery life values requirements and IEC 60601-2-66:2019.

Mechanical Testing

The Concha Sol Hearing Aid mechanical design was tested extensively to verify its design criteria and performance with respect to the mechanical system specifications and properties in support of reasonable assurance of safety and effectiveness. The Concha Sol Hearing Aid, including Ear Tips were tested in finished form and passed Packaging and Environmental testing.

Transportation

Simulations of transport of the Concha Sol Hearing Aids' packaging to remain intact during testing per ASTM 599, ASTM 5276 and ASTM 4169 DC-13. All requirements were met.

Human Factors/Usability

Concha Labs assessed its hearing aid for usability and human factors to provide reasonable assurance of the usability engineering process and to mitigate risks caused by usability problems per its intended use. The company performed a series of three iterative usability evaluations (Formative Studies 1, 2 and 3) during the development of the hearing aid and companion Concha Labs mobile app. Participants met the device criteria for an intended user. Key findings and device/labeling modifications were implemented to the user interface design in response to the studies.

Summative Human factors were validated across two primary studies.

- Human factors/usability validation test in which 15 representative users attempted all critical and essential tasks in the context of realistic use scenarios;
- Self-selection validation study in which 27 potential consumers determined if the hearing aid was appropriate for their needs based on pre-screening information (e.g., outside package labeling, etc.).

The validation of human factors/usability aspects of the device included 15 representative users ranging in age from 25 – 76 (median age of 70) and included 10 females/5 males with 2/3 of all participants aged 60 and above. Five participants self-described a mild hearing loss and 10 indicated a moderate with 9/15 indicating no prior hearing aid experience.

Assessment to determine if potential users can make a correct self-selection decision (suitability of Concha Sol for their personal use) based on their perceived level of hearing loss, presence or absence of contraindications after only having access to review Concha Labs website or product packaging.

After analysis of data per pre-specified 'success' outcomes it was determined that the Concha Sol Hearing Aid and Concha app are able to be used correctly by the intended users under the anticipated condition of use.

Clinical Performance Testing

The objective of the within-subject, randomized, crossover study design of the clinical investigation was to assess and evaluate the performance and clinical effectiveness of the Concha Sol self-fitting hearing aid, according to two distinct fitting methods. The first method involved users fitting the hearing aid devices themselves by relying exclusively on the provided iOS smartphone application (Concha Labs App), without any support from a hearing care professional (SELF-FIT). The second method used the same hearing devices, but it was clinically fitted by a hearing care professional following industry best practices (CLIN-FIT).

STUDY PARTICIPANT DEMOGRAPHICS

Demographically, the study participants included a representative mix of female/male, age, and prior experience with hearing aids.

SEX	NUMBER
MEN	13
WOMEN	8

AGE,	YEARS
MEAN (SD)	66.2
MEDIAN (IQR)	73.0

HA EXPERIENCE	NUMBER
INEXPERIENCED USERS	17
EXPERIENCED USERS	4

Additionally, the 'indications for use' of the Concha Sol Hearing Aid stated the intended users have a perceived mild to moderate hearing loss. As part of the study protocol, audiometric measures were taken and indicated that their hearing was consistent with that target population (perceived mild-to-moderate) hearing status.

STUDY ENDPOINTS AND SUCCESS CRITERIA

Effectiveness:

A standardized measure of speech communication in noise, the Quick Speech-in-Noise (QuickSIN) Test was used as the primary effectiveness endpoint. A secondary effectiveness endpoint, the Abbreviated Profile of Hearing Aid Benefit (APHAB) was used to evaluate the effect on hearing impairment or benefit in daily life. Note that for each intervention, endpoints were measured at the end of the two-week take-home field trial.

Following previous studies investigating the effectiveness of self-fitting relative to clinician-fitting (including the predicate device study; Sabin et al., 2020), a margin of 1.8 dB was defined for the QuickSIN benefit, and a margin of 9.9 for the APHAB. For the clinical study to be deemed successful, the SELF-FIT method needs to yield outcomes (namely QuickSIN and APHAB scores) which are comparable to the CLIN-FIT method. For both assessed endpoints, the study results indicated comparable performance and satisfaction outcomes as revealed from clinical data as compared to the same hearing aid fit by a clinician.

Safety:
No device-related or other adverse events were observed over the course of the study. Also, no health-related issues due to device fit or discomfort were observed, and no device failures leading to potential safety issues were observed. These results support that the subject hearing aids are safe for its intended users.

The clinical study has demonstrated that the Concha Sol hearing aids are comparably safe and effective for their intended use and are substantially equivalent to the Bose predicate device.

The Concha Sol hearing aids have the same intended use and indications with similar technological characteristics and principles of operation as its predicate device and any differences raise no new questions of safety and effectiveness when compared to the predicate.

Conclusion:
The Concha Sol OTC Hearing Aid has the same intended use and indications for use compared to the predicate device with comparable technological characteristics and principles of operation that do not raise different questions of safety and effectiveness compared to the predicate device. Non-clinical performance testing demonstrated comparable safety and effectiveness with respect to electrical safety, EMC and electroacoustic testing as compared to the primary predicate, Bose SoundControl Hearing Aid (K211008). Similarly, software was developed, tested, and documented in accordance with software development and testing pursuant to IEC 62304:2006+A1:2015, FDA's "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices" (2005), and demonstrated that the Concha Sol Hearing Aid should perform as intended in the specified use conditions consistent with that reported by the predicate, the Bose SoundControl Hearing Aid.

The usability testing and clinical study provided evidence of clinically meaningful benefit to a population experiencing obstacles to accessibility and affordability of hearing aids. The evidence of clinical effectiveness (verified both quantitatively and qualitatively) validates that the Concha Sol Hearing Aid performs comparably to the clinical effectiveness of the predicate device. The Concha Sol Hearing Aid is substantially equivalent in intended use to the Bose SoundControl Hearing Aid (K211008).