February 9, 2024

Wsaud A/s
% John Smith
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K233464
Trade/Device Name: WSA Self-Fitting Hearing Aid Gen 2
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QUH
Dated: October 23, 2023
Received: January 11, 2024

Dear John Smith:

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233464

Device Name

WSA Self-Fitting Hearing Aid Gen 2

Indications for Use *(Describe)*

The WSA Self-Fitting Hearing Aid Gen 2 is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs through software tools. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

The SF-App is intended to support self-fitting and fine-tuning of the hearing aid.

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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WSAudiology

510(k) Summary
K233464

1. Submitter

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Contact Person: La-Shaunda Joseph, US Regulatory Affairs Manger
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Date Prepared: February 9, 2024

2. Subject Device

Device Proprietary Name:	WSA Self-Fitting Hearing Aid Gen 2
Common or Usual name:	Hearing Aid
Classification Name:	Self-Fitting Air-Conduction Hearing Aid
Regulatory Number:	21 C.F.R. § 874.3325
Product Code:	QUH (Self-Fitting Air-Conduction Hearing Aid, Over The Counter)
Device Classification:	Class II

3. Predicate Device:

WSAUD A/S's Vibe SF Self-Fitting Hearing Aid (K220403)

4. Device Description

The WSA Self-Fitting Hearing Aid Gen 2 ("SF Gen 2") is a self-fitting air conduction hearing aid 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.

The SF Gen 2 hardware includes: Earpieces (sleeves), housing, circuit board including a chip set running embedded software, antenna for near-field magnetic inductive wireless connection for data exchange between the left and right hearing aids, rechargeable battery, and electroacoustic components. The instant fit in-the ear (ITE) style of the hearing aids uses sleeves in 4 different sizes to couple with the ear canal. The sleeves are available in vented and closed styles. The hearing aids are powered by built-in rechargeable Lithium-Ion batteries. The device includes embedded software that communicates with the self-fitting software app.

The SF Gen 2 self-fitting system consists of: (a) a wireless hearing aid with a self-fitting feature, and (b) a software application to support hearing aid self-fitting and fine tuning. The subject device is fitted for bilateral use. Left and right hearing aids can communicate with

each other over a magnetic inductive wireless link, and the hearing aids communicate with the self-fitting web application (the “self-fitting app”) using acoustic technology.

The SF Gen 2 self-fitting app is run on an Internet browser that is integrated into a software app that is downloaded onto and accessed through the user’s mobile device. The self-fitting strategy begins with an acoustic profiling test that the user performs while wearing the hearing aids. Based on the user’s hearing profile, a “cluster” of initial settings is applied to each hearing aid, and users are then guided through fine-tuning of these settings to self-fit the hearing aids for their particular needs and comfort. The mobile app also allows the user to adjust audiological gain parameters and preferred settings on the hearing aid, and functions as a remote control for adjusting hearing aid volume during daily use.

5. Indications for Use

The WSA Self-Fitting Hearing Aid Gen 2 is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user’s hearing needs through software tools. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

The SF-App is intended to support self-fitting and fine-tuning of the hearing aid.

6. Comparison of Technological Characteristics

Both the subject and predicate devices are self-fitting hearing aids indicated for individuals 18 years of age and older with perceived mild to moderate hearing impairment. The same fundamental technology is present in both hearing aids to allow the user to control and customize the device to the user’s hearing needs. Both devices are instant fit in-the ear (ITE) hearing aids designed for all-day wear. At a high level, the subject and predicate devices are based on the following same technological elements:

- Self-fit hearing aid.
- Home healthcare environment use.
- Software to support self-fitting and fine-tuning of the hearing aid.
- Software platform compatibility (iOS, Android).

Both devices use the same communication technology, including near-field magnetic inductive wireless link for data exchange between the left and right hearing aid, and acoustic technology for communication between the hearing aids and the self-fitting app. Additionally, both employ the same self-fitting strategy, which is implemented using a web-based application (the “self-fitting app”).

The main design differences between the subject and predicate devices are:

- The self-fitting app is accessed through a web browser embedded in a dedicated mobile app for the hearing aid, rather than through a standalone web browser.
- Change in the number of clusters that can be applied as a starting point for the user’s own fine-tuning, from 4 clusters in the predicate to 6 in the subject device.
- Subject device is powered by rechargeable Lithium-Ion batteries, whereas the predicate device used disposable Zinc-Air hearing aid batteries.
- Subject device uses an updated chip set and updated embedded software.

- Subject device conforms to new labeling requirements for OTC hearing aids under 21 CFR 800.30.

A table comparing the key features of the SF Gen 2 to the predicate is provided below.

Comparison of Subject and Predicate Devices

Property	**Subject Device:** *WSA Self-Fitting Hearing Aid Gen 2*	**Predicate Device** *Vibe SF Self-Fitting Hearing Aid* (K220403)	**Comparison**
Product Code	QUH	QDD	Supports substantial equivalence ("SE") given change in hearing aid regulations since clearance of predicate.
Classification Regulation	21 CFR 874.3325	21 CFR 874.3325	Same
Indications for use	The WSA Self-Fitting Hearing Aid Gen 2 is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs through software tools. The device is intended for Direct-to-consumer sale and use without the assistance of a hearing care professional. The SF-App is intended to support self-fitting and fine-tuning of the hearing aid.	The Vibe SF self-fitting hearing aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs through software tools. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional. The EasyFit self-fitting web application is intended to support self-fitting and fine-tuning of the Vibe SF hearing aid.	Same
Power Source	Built-in Lithium-Ion rechargeable battery	Disposable zinc-air battery	Supports SE. Testing shows rechargeable battery is safe.
Labelling	Includes applicable requirements of 21 CFR 800.30.	Includes applicable requirements of 21 CFR 801.420 and 801.421.	Supports SE given change in hearing aid regulations since clearance of predicate.
Acoustic Characteristics	Max OSPL 90: 114 dB SPL Fitted OSPL 90: 99 dB SPL Full-on gain: 44 dB	Max OSPL 90: 114 dB SPL Fitted OSPL 90: 103 dB SPL Full-on gain: 45 dB	Supports SE. Both are adequate for fitting moderate hearing loss (55 dB HL) as prescribed by NAL-NL2.
Frequency Range	250 – 8000 Hz or 100-9100 Hz (depending on measurement method)	100 – 8600 Hz	Supports SE. Both are adequate for fitting moderate hearing loss as prescribed by NAL-NL2.
Input Noise	23 dBA	20 dBA	Supports SE. Both comply to the required

Property	Subject Device: *WSA Self-Fitting Hearing Aid Gen 2*	Predicate Device *Vibe SF Self-Fitting Hearing Aid* (K220403)	Comparison
			self-generated noise limit of 32 dB A per 21 CFR 800.30(e)(2).
Clusters	6	4	Does not affect SE. Change does not significantly affect self-fitting process.
Chip Platform:	Version D12+ with a modified analog front-end chip, digital signal processing chip and embedded software	Version D11	Does not affect SE. Testing confirms the differences do not affect self-fitting functionality.
Self-Fitting App	Web application running on a browser integrated into the mobile app	Web application running on standard web browser on mobile phone	Supports SE. Different way of accessing the app does not change functionality.

7. Performance Testing

Performance testing, summarized below, was conducted to demonstrate that the SF Gen 2 is as safe and effective as the predicate.

WSAUD conducted a series of non-clinical tests on the SF Gen 2 to assess electrical safety, EMC, wireless coexistence, electroacoustic performance, biocompatibility, and software verification/validation. Device and application firmware and software have been validated per the same standards used to validate the predicate's device and application firmware and software. The results are summarized in the table below:

Performance Testing

Property	Test	Result
IEC 60601-1 Ed. 3.2:2020 IEC 60601-1-2 Ed. 4.1:2020 IEC 60601-1-11 Ed. 2.1:2020 IEC 60601-2-66 Ed. 3.0:2019	EMC and Electrical Safety	Pass
AAMI TIR 69:2017 ANSI C63.27:2021	Wireless Functionality and Coexistence	Pass
ANSI/ASA S3.22:2014 ANSI/CTA 2051:2017 21 CFR § 800.30	Electroacoustic Performance	Pass
IEC 62304 A1:2016	Software Verification / Validation	Pass
IEC 62133-2:2017 UL 1642:2014	Battery Safety	Pass
ISO 14971:2019 AAMI TIR57:2016	Risk Assessment	Pass

In all instances, the SF Gen 2 functioned as intended and results observed were as expected.

The self-fitting strategy is unchanged in the SF Gen 2 compared to the Vibe SF. Although the SF Gen 2 has a minor modification to the “clusters” of hearing aid settings that are applied after the user’s hearing profile test, these clusters are not intended to provide final settings for users, but rather to provide a starting point for the user’s own fine-tuning. Therefore, the modification to the clusters does not constitute a change in the self-fitting strategy, and no new clinical performance testing was required.

8. Conclusion

The WSA Self-Fitting Hearing Aid Gen 2 is as safe and effective as the predicate Vibe SF Self-Fitting Hearing Aid (K220403). The WSA Self-Fitting Hearing Aid Gen 2 has the same intended use indications for use, and similar technological characteristics and principles of operation as its predicate device. In addition, the minor technological differences between the subject and predicate devices raise no new issues of safety or effectiveness. Therefore, the SF Gen 2 is substantially equivalent to the predicate device.