



January 31, 2025

Luxottica Group S.P.A.  
John Luna  
Executive Advisor  
Piazzale Cadorna 3  
Milan, 20123  
Italy

Re: K243150

Trade/Device Name: Nuance Audio Hearing Aid Software  
Regulation Number: 21 CFR 874.3335  
Regulation Name: Air Conduction Hearing Aid Software  
Regulatory Class: Class II  
Product Code: SCR  
Dated: September 27, 2024  
Received: September 30, 2024

Dear John Luna:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SRINIVAS NANDKUMAR -S

Srinivas Nandkumar, Ph.D.

Director

DHT1B: Division of Dental and  
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K243150

Device Name

Nuance Audio Hearing Aid Software

Indications for Use (Describe)

The Nuance Audio Hearing Aid Software is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The software utilizes a preset fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use.

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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# Nuance Audio Hearing Aid Software

## 510(k) Summary

### 1. DEVICE [PER 807.92(a)(2)]

**Name of Device:** Nuance Audio Hearing Aid Software

**Classification Name:** Air Conduction Hearing Aid Software

**Common Name:** Hearing Aid Software

**Regulation:** 21 CFR §874.3335

**Regulatory Class:** II

**Product Code:** SCR

### 2. PREDICATE DEVICE [PER 807.92(a)(3)]

**Predicate:** Apple Hearing Aid Feature (HAF) DEN230081

This predicate has not been subject to a design-related recall.

### 3. DEVICE DESCRIPTION [PER 807.92(a)(4)]

The Nuance Audio Hearing Aid Software is a software-only device that is comprised of a pair of software modules which operate on two separate required products: (1) Nuance Audio Application on a compatible iOS or Android product, and (2) Nuance Audio Hearing Aid Software Firmware (FW) using the compatible wearable electronic computing platform, the Nuance Audio Glasses (smart glasses). See image 1.

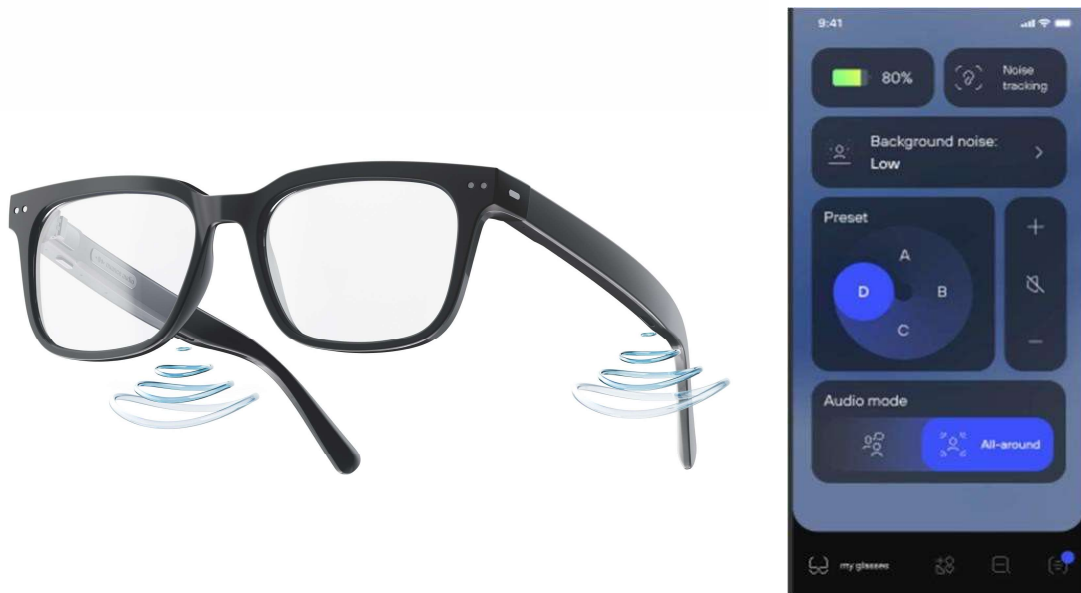


Image 1

The Nuance Audio Hearing Aid Software amplifies sounds for adult users, 18 years of age and older, who have a perceived mild to moderate hearing loss. The Nuance Audio™ App, iOS or Android mobile application, guides the user through the initial onboarding and set up process providing step-by-step instructions to guide the users. The users can select from four preset options, which are generated from typical mild to moderate hearing loss configurations (Urbanski et al., 2021) with NAL-NL2 gain settings applied. These audiogram hearing loss profiles have been validated as being appropriate for individuals with mild to moderate hearing loss. Therefore, this provides support for their use in deriving the presets for this device for the intended user population of individuals with perceived mild to moderate hearing loss. Note that the output of an individual user's hearing test is not used in the fitting of this device.

The different preset listening profiles are represented as Preset A, B, C, and D, respectively, as shown in the software interface below (Image 2; Nuance Audio Hearing Aid Software). The user may also adjust the overall volume, noise reduction, and microphone directionality. The device incorporates a feedback control algorithm to reduce the likelihood of the user experiencing acoustic feedback. The same amplification settings will be applied to both the left and right ear. This device can be fitted by a user without assistance from a hearing healthcare professional.

NOTE: Nuance Audio Glasses refers to the compatible hardware platform together with the hearing aid functionality enabled software.

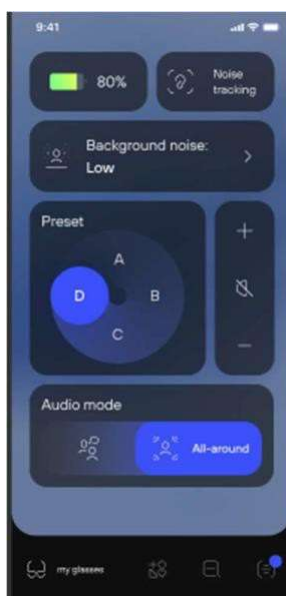


Image 2: Nuance Audio™ App Main Screen for iOS and Android

#### 4. INTENDED USE

The Nuance Audio Hearing Aid is a software-only mobile medical application that is intended to be used with a compatible wearable electronic computing platform. The Nuance Audio Hearing Aid Software is intended to amplify sounds for individuals 18 years of age or older with perceived mild to moderate hearing loss. The Nuance Audio Hearing Aid Software also allows for user customization to suit their perceived hearing needs through utilizing 4 pre-set fitting options based

on typical hearing loss profiles of a mild to moderate hearing loss (Urbanski et al, 2021). The presets are selected subjectively by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The Nuance Audio Hearing Aid Software device is intended for over-the-counter (OTC) use.

## 5. INDICATIONS FOR USE

The Nuance Audio Hearing Aid Software is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing loss. The software utilizes a preset fitting options and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for over-the-counter (OTC) use.

## 6. Comparison of Intended Use and Technological Characteristics with the Predicate

A comparison of the intended use and technological characteristics, e.g., features, parameter settings etc. of the subject device to the predicate (see **Table 1**) begins with the *intended use* and then summarizes the technological characteristics of the Nuance Audio Hearing Aid Software in comparison to the predicate, the Apple Hearing Aid Feature (HAF). Both are software devices that are intended to amplify sound for individuals 18 and older with perceived mild to moderate hearing loss. The form factor and fitting strategies have differences and the description of the similarities and the strategies employed to address those differences is explained below in Section 8.

**Table 1.**  
Summary of Substantial Equivalence

|                            | <b>Subject Device</b>                                                                                                                                                                                                                                                                                                                                | <b>Predicate Device</b>                                                                                                                                                                                                                                                                                                        | <b>Discussion</b>                                                                                                                                                                                                                 |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Device Trade Name</b>   | <b>Nuance Audio Hearing Aid Software</b>                                                                                                                                                                                                                                                                                                             | <b>Hearing Aid Feature (HAF)</b>                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                   |
| <b>FDA Number</b>          | K243150                                                                                                                                                                                                                                                                                                                                              | DEN230081                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                   |
| <b>Product code</b>        | SCR                                                                                                                                                                                                                                                                                                                                                  | SCR                                                                                                                                                                                                                                                                                                                            | Same as predicate                                                                                                                                                                                                                 |
| <b>Regulation Number</b>   | 21 CFR 874.3335                                                                                                                                                                                                                                                                                                                                      | 21 CFR 874.3335                                                                                                                                                                                                                                                                                                                | Same as predicate                                                                                                                                                                                                                 |
| <b>Regulation name</b>     | Air-Conduction Hearing Aid Software                                                                                                                                                                                                                                                                                                                  | Air-Conduction Hearing Aid Software                                                                                                                                                                                                                                                                                            | Same as predicate                                                                                                                                                                                                                 |
| <b>Indications for Use</b> | The Nuance Audio Hearing Aid Software is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing loss. The software utilizes a preset fitting strategy and is | The Hearing Aid Feature is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Hearing Aid Feature utilizes a self- | Both devices have the same intended use for the same target population (adults with a perceived mild to moderate hearing loss). Both devices can be fitted by a user without the assistance of a hearing healthcare professional. |



|  |                                                                                                                                                                |                                                                                                                                                                                        |  |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for over-the-counter use. | fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use. |  |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|                          | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                               | Predicate                                                                                                                                                           | Discussion                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device Trade Name        | Nuance Audio Hearing Aid Software                                                                                                                                                                                                                                                                                                                                                                                                                            | Hearing Aid Feature (HAF)                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Wearable Platform</b> | The Nuance Audio Hearing Aid Software is housed in the frames of a commercial pair of smart glasses, the Nuance Audio Glasses. The microphones and speakers are in the frames' temple pieces, with the speakers directing the amplified sound to the ear canal providing the user with an open ear canal listening experience. Nuance Audio Glasses refers to the compatible hardware platform together with the hearing aid functionality enabled software. | The HAF software is housed in the Apple AirPods Pro 2, a consumer electronic earbud. The amplified sound is delivered via an ear-tip situated inside the ear canal. | Differences in wearable and firmware platform. The Nuance Audio Glasses deliver the air-conducted signal without the device obstructing the ear canal, whereas the predicate device uses a compatible hardware that resides within the concha and ear canal. Performance testing evaluated these differences in technology and the results support substantial equivalence. Clinical performance data of the subject device is presented in Section 8, Statement of Substantial Equivalence. |



|                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Fitting method</b>           | <p>The Nuance Audio App, iOS or Android mobile application, guides the user through the initial onboarding and set up process providing step-by-step instructions to guide the users. The users can select from four preset options, which are generated from typical mild to moderate hearing loss configurations (Urbanski et al., 2021) with NAL-NL2 gain settings applied. These amplification profiles have been validated as being appropriate for individuals with mild to moderate hearing loss. Note that the output of an individual user's hearing test is not used in the fitting of this device. The different preset amplification profiles are represented as Preset A, B, C, and D, respectively.</p> <p>The user may also adjust the overall loudness, noise reduction, and microphone directionality using the Nuance Audio App. Additionally, the user can access volume adjustments via the multifunction button on the Nuance Audio Glasses. The same amplification settings will be applied the for the left and right ear. This device can be fitted by a user without assistance from a hearing healthcare professional.</p> | <p>The Apple HAF requires the user to select a hearing test result from the Health app on the iOS device. Once the HAF onboarding is completed, then fine-tuning becomes available to the user.</p> <p>There are three types of adjustments (Amplification, Tone and Balance) that the user can make to optimize their hearing preferences.</p> <p>Descriptions of the three fine-tuning sliders can be found below:</p> <ol style="list-style-type: none"> <li>1. Amplification - Makes the sounds louder or quieter</li> <li>2. Tone - Changes the amount of high and low pitch sounds (e.g. modify the 'brightness' of the sound).</li> <li>3. Balance - Adjusts the ratio of sound level between the left and right AirPods Pro 2 earbuds.</li> </ol> <p>The user is able to adjust the fine-tuning settings anytime on a compatible iPhone, iPad, MacBook or Apple Watch.</p> | <p>The subject device incorporates a preset fitting method while the predicate uses a self-fitting strategy. Both the subject and predicate device meet the amplification needs for their intended users. Performance testing evaluated these differences in technology and the results support substantial equivalence, including 800.30(e). Clinical performance data of the subject device is presented in Section 8, Statement of Substantial Equivalence.</p> |
| <b>Input Signal compression</b> | Wide dynamic range compression                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Wide dynamic range compression                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Similar to predicate                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Microphones</b>              | Microphones are in the temples of the Nuance Audio Glasses'. During use, can be configured by the user in omnidirectional (all-around) or directional (frontal) modes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Dual beamforming microphones and an inward facing microphone.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Similar to predicate. Performance testing evaluated these differences in technology and the results support substantial equivalence, including 800.30(e).                                                                                                                                                                                                                                                                                                          |

|                                |                                                                        |                                                                           |                      |
|--------------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------------|----------------------|
| <b>Battery Technology</b>      | Rechargeable lithium-ion battery                                       | Rechargeable lithium-ion battery                                          | Same as predicate    |
| <b>Battery Lifetime</b>        | Battery life of ~6 hrs. per battery single charge for hearing aid use. | Battery life of ~6 hrs. per battery single charge for hearing aid feature | Same as predicate    |
| <b>Active Noise Reduction</b>  | Present                                                                | Present                                                                   | Similar to Predicate |
| <b>Mobile App</b>              | Mobile application on a compatible iOS or Android operating platform.  | Mobile application on a compatible iOS operating platform.                | Similar to Predicate |
| <b>Remote firmware updates</b> | The subject device allows for remote firmware updates.                 | The predicate allows for remote firmware updates.                         | Same as Predicate    |

| <b>Electro-Acoustic Characteristics</b> | <b>Subject Device</b>                    | <b>Predicate</b>                 | <b>Discussion</b>                                                                                                                                           |
|-----------------------------------------|------------------------------------------|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                         | <b>Nuance Audio Hearing Aid Software</b> | <b>Hearing Aid Feature (HAF)</b> |                                                                                                                                                             |
| <b>Latency Clause</b>                   | 8.8 ms                                   | 3.15 ms                          | The subject meets 21CFR 800.30 requirements. Performance testing evaluated these differences in technology and the results support substantial equivalence. |
| <b>Frequency Response</b>               | 200Hz - 6300 Hz                          | 100 – 10,000 Hz                  | The subject meets 21CFR 800.30 requirements. Performance testing evaluated these differences in technology and the results support substantial equivalence. |

|                                                                       |                          |                          |                                                                                                                                                             |
|-----------------------------------------------------------------------|--------------------------|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Self-Generated Noise Value</b>                                     | 29.9 dBA                 | 28 dBA                   | The subject meets 21CFR 800.30 requirements. Performance testing evaluated these differences in technology and the results support substantial equivalence. |
| <b>Harmonic Distortion</b>                                            | Less than or equal to 1% | Less than or equal to 1% | The subject meets 21CFR 800.30 requirements. Performance testing evaluated these differences in technology and the results support substantial equivalence. |
| <b>Maximum Output Value (Output Sound Pressure Level 90) (OSPL90)</b> | 112.7 dB SPL             | 106 dB SPL               | The subject meets 21CFR 800.30 requirements. Performance testing evaluated these differences in technology and the results support substantial equivalence. |

## 7. Performance Testing

Both the subject and predicate devices were tested for conformity to the following FDA recognized consensus standards applicable to OTC hearing aids for their intended use.

### Biocompatibility

- ISO 10993-1 Biological evaluation of medical devices
- ISO 10993-5 Biological evaluation of medical devices
- ISO 10993-10 Biological evaluation of medical devices
- ISO 10993-12 Biological evaluation of medical devices

### Electro-Acoustics

- ANSI/ASA S3.22 2014 Measurements
- CTA 2051:2017

### Electrical Safety, EMC, Battery Safety, Software and Labeling

- IEC 60601-1; 2005 + AMDI:2012; + AMD2: 2021
- IEC 60601-1-2; 2014, AMDI:2020; Part 1-2
- IEC 60601-2-66: 2019
- ISO 15223-1:2021\_4th edition
- IEC 62304:2006; 1st Edition +A1:2016

Consistent with the predicate, the Nuance Audio Hearing Aid Software passed all relevant non-clinical performance testing and biological endpoints with the representative, compatible computing platform hardware (smart glasses) being verified that the amplified acoustic signal output by the hardware platform is calibrated.

Similarly, software verification and validation, bench performance testing against established consensus standards for electrical safety, EMC and battery safety were conducted with the representative, compatible hardware (smart glasses) to verify the amplified acoustic signal output by the hardware platform.

Confirmatory bench testing relating to insertion gain was conducted to help support substantial equivalence of the subject device to the predicate. Insertion gain using an International Speech Test Signal (ISTS) was measured at 65 dB SPL from 250Hz to 5000Hz for both the Nuance Audio Glasses and the Apple AirPods Pro 2 devices (side-by-side testing) using a head and torso simulator (HATS). Both the subject and predicate devices were fit using the audiometric thresholds from Hearing Loss Profile 3 from Urbanski et al. (2021). This hearing profile is a sloping mild to moderate hearing loss (Urbanski et al, 2021; Hearing Loss Profile 3). This corresponds to Preset C for the Nuance Audio Hearing Aid Software. The subject device insertion gains were within 5 dB of the predicate device at most frequencies under these test conditions. In addition to the comparative testing, the subject device insertion gains were within 5 dB of the NAL-NL2 targets except at one frequency (5 kHz, within 8 dB).

### Usability Testing

Per Special Control 3 and as an OTC medical device intended to be used without the support of a hearing healthcare professional, the Nuance Audio Hearing Aid Software was assessed in compliance with IEC 62366:2015 to complete human factors/usability validation. The 15 representative adult users in the study participated in key use scenarios that included critical and essential tasks that were necessary to provide the appropriate context of use. They were all novice users of hearing technology and were of varying ages (24 – 58 yrs.).

The specific objectives of this human factors engineering / usability engineering validation test were as follows:

- Demonstrate that the device and its associated components/accessories can be used successfully in simulated use scenarios by utilizing manufacturer provided identification of intended users and use environments, indications and contraindications for use, multiple media instructional information to effectively and safely operate the device in different use environments; and
- ensure that the use-related safety issues associated with the Nuance Audio Glasses have been adequately mitigated.

The 15 representative users were able to complete all tasks without critical errors and expressed an overall positive satisfaction on the usability of the device. All defined acceptance criteria were met (EN 62366-1:2015).

## **8. Statement of Substantial Equivalence**

The Nuance Audio Hearing Aid Software has the same intended use and indications for use compared to the predicate, Hearing Aid Feature (HAF) with differences in the technological characteristics and principles of operation. These differences do not raise different questions of safety and effectiveness than those of the predicate device. However, performance data was provided to address these differences in technology and support substantial equivalence to the predicate.

The Nuance Audio Hearing Aid Software is housed in the frames of a commercial pair of smart glasses,

the Nuance Audio Glasses. The microphones and speakers are in the frames' temple pieces, with the speakers directing the amplified sound to the ear canal providing the user with an open ear canal listening experience. Nuance Audio Glasses refers to the compatible hardware platform together with the hearing aid functionality enabled software. The predicate device uses a compatible hardware that resides within the concha and ear canal. Specifically, the HAF software is housed in the Apple AirPods Pro 2, and the amplified sound is delivered via an ear-tip situated inside the ear canal. The Nuance Audio Glasses are a novel way to provide amplification for those users with a perceived mild to moderate hearing loss who don't wish to wear a device in their ear canal. The subject device has met the same Technical Specifications and electro-acoustic requirements as the predicate device, and any difference due to the subject device wearable platform (i.e., Nuance Audio Glasses) have been verified by clinical and non-clinical performance measurements.

The Nuance Audio Hearing Aid Software is different in fitting method to the predicate device in that the subject device provides the user clinically validated preset options using four pre-determined audiogram profile presets (Urbanski et al, 2021), whereas the HAF utilizes a self-fitting strategy with audiogram input. While the methodologies are different operationally, the end user still has the ability to acquire and use an OTC hearing aid that can be fit without professional healthcare assistance. The Nuance Audio Hearing Aid Software was shown to meet the specifications associated with over-the-counter hearing aids (21 CFR 800.30).

The Nuance Audio Hearing Aid Software also meets the special controls for 874.3335. Special control number 1 under 874.3335 requires clinical performance data to validate a hearing aid software's self-fitting strategy. In this case, the Nuance Audio Hearing Aid Software does not have a self-fitting strategy, as it uses preset programs to fit the user. However, additional performance data (including clinical data) was provided to evaluate the differences in technology (preset vs. self-fitting) in evidence to support that the subject device and predicate were substantially equivalent.

- Real-ear measurements were assessed using subject device and compared to a commonly used clinical fitting formula (NAL-NL2). The real-ear aided response (REAR) of 29 participant ears was compared to NAL-NL2 targets at 250, 500, 1000, 2000, and 4000Hz. The results showed that each Nuance Audio Hearing Aid Software preset (A, B, C, and D) profile was within the pre-specified criterion range of NAL-NL2 targets ( $\pm 6$  dB).
- Speech in noise clinical performance of the Nuance Audio Hearing Aid Software using Nuance Audio Glasses was conducted with 19 adults with mild to moderate hearing loss to determine the signal-to-noise ratio at which the user can recognize and repeat 50% of the words (SNR-50). Results of the speech-in-noise testing demonstrated the average unaided vs. aided improvement was 3.49 dB.
- A patient reported outcome measure, the International Outcome Inventory for Hearing Aids (IOI-HA; Cox, 2002) was conducted on 23 adult subjects after a 14-day trial with the Nuance Audio Glasses. The subjects were identified as having self-perceived mild-to-moderate sensorineural hearing loss. The mean IOI-HA total score was 29.04 (SD = 4.62). This outcome score is considered to be clinically meaningful for the intended population, such that individuals with perceived mild to moderate hearing loss may achieve hearing benefit from using this device.

The difference in preset vs. self-fitting strategy between the subject and predicate devices do not introduce different questions of safety and effectiveness, as both devices meet the amplification needs for the target population with perceived mild to moderate hearing loss. The Nuance Audio Hearing Aid Software is substantially equivalent in intended use with differences in technological characteristics to the predicate device, Hearing Aid Feature (DEN230081).