DE NOVO CLASSIFICATION REQUEST FOR HEARING AID FEATURE

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Air-conduction hearing aid software. Air-conduction hearing aid software is a device that is intended to be used with a compatible wearable hardware platform to compensate for impaired hearing. The software also allows for customization to the user's hearing needs. Devices in this classification are also subject to the requirements in § 800.30 or § 801.422 of this chapter, as applicable. This classification does not include software that is used with hardware as part of a hearing-aid device system classified in other regulations, e.g., § 874.3300, § 874.3305, or § 874.3325.

NEW REGULATION NUMBER: 21 CFR 874.3335

CLASSIFICATION: Class II

PRODUCT CODE: SCR

BACKGROUND

DEVICE NAME: Hearing Aid Feature

SUBMISSION NUMBER: DEN230081

DATE OF DE NOVO: December 4, 2023

CONTACT: Apple Inc.
One Apple Park Way
Cupertino, CA 95014

INDICATIONS FOR USE

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-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.

LIMITATIONS

The following important information on device use are included in the Instructions for Use:

Important Information from the Instructions for Use:

WARNING: If you are younger than 18, DO NOT use this.

- You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older

The Hearing Aid Feature is for adults with signs of mild to moderate hearing loss. How do you know if you have this?

- You have trouble hearing speech in noisy places
- You find it hard to follow speech in groups
- You have trouble hearing on the phone
- Listening makes you tired
- You need to turn up the volume on the TV or radio, and other people complain it's too loud

Some people with hearing loss may need help from a hearing healthcare professional even after using this Hearing Aid Feature. How do you know if you need to see one?

- You can't hear speech even if the room is quiet
- You don't hear loud sounds well, for example, you don't hear loud music, power tools, engines, or other very noisy things
- If this hearing aid does not help you enough, ask for help from a hearing healthcare professional

WARNING: When to See a Doctor

- If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT)
  - Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident
  - You saw blood, pus, or fluid coming out of your ear in the past 6 months
  - Your ear feels painful or uncomfortable
  - You have a lot of ear wax, or you think something could be in your ear
  - You get really dizzy or have a feeling of spinning or swaying (called vertigo)
  - Your hearing changed suddenly in the past 6 months
  - Your hearing changes: it gets worse then gets better again
  - You have worse hearing in one ear
  - You hear ringing or buzzing in only one ear

CAUTION: The sound output should not be uncomfortable or painful

- You should turn down the volume or remove the AirPods Pro if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust the Hearing Aid Feature settings.

If you remain concerned, consult a professional

- If you try the Hearing Aid Feature and continue to struggle with or remain concerned

about your hearing, you should consult with a hearing healthcare professional.

What you might expect when you start using Apple's Hearing Aid Feature

- A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.
- People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.
- If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening - for example, noisy environments.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Hearing Aid Feature (HAF) is a software-only device that is comprised of a pair of software modules which operate on two separate required products: (1) HAF iOS Application on a compatible iOS product, and (2) HAF software (i.e., firmware) on the Apple AirPods Pro 2. Refer to Figure 1, middle and right, respectively. The AirPods Pro 2, formerly named AirPods Pro (2nd generation), supported this granting and are hereafter simply referred to as "AirPods Pro" in this document.

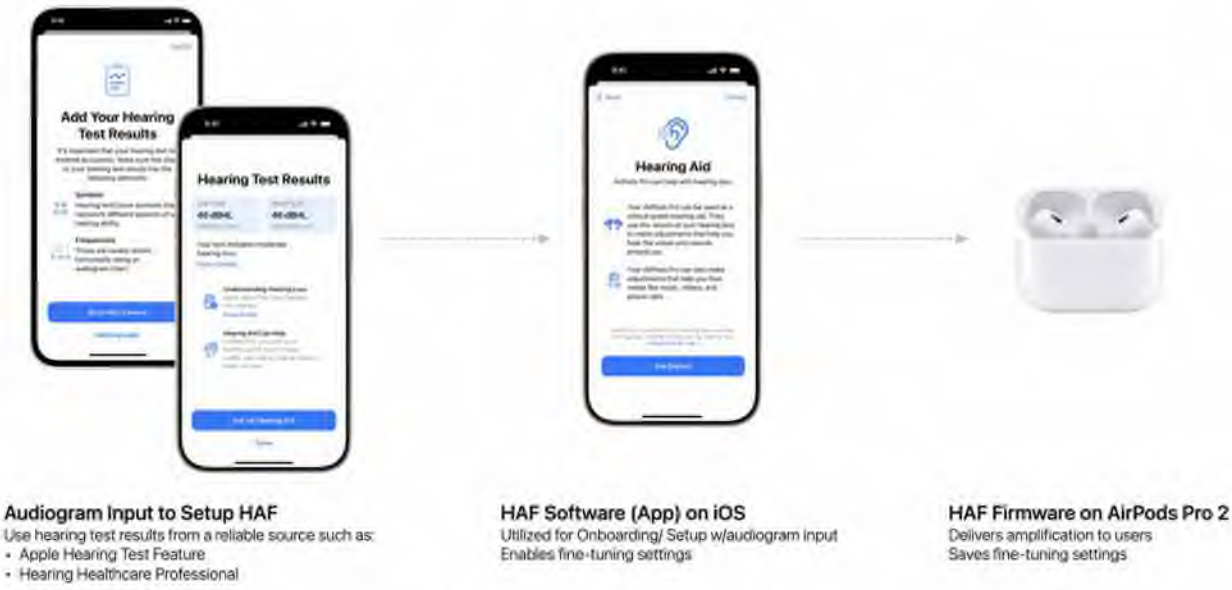

Figure 1: Audiogram input to HAF (left), HAF Software Application on iOS product (middle) & HAF Software (i.e., Firmware) on AirPods Pro (right)

The HAF iOS Application guides users through the onboarding and setup process for the HAF. The process is self-guided by the user and includes step-by-step instructions and informational content (e.g. warnings, instructions for use). To initiate HAF setup, the user must select a saved audiogram from the iOS HealthKit[1] (Figure 1, left). Users are instructed to select an audiogram obtained from a reliable source (e.g. Apple's Hearing Test Feature[2] or from a hearing healthcare professional). Compatible audiograms must contain results at 250, 500, 1000, 2000, 4000, and 8000 Hz and meet other minimum quality requirements. During HAF onboarding, users are required to verify their age and are provided with educational material, including warnings and information required by 21 CFR 800.30.

Once the audiogram has been imported by the HAF, the feature will configure the amplification for the user's audiogram based upon Apple's proprietary fitting formula. Once the initial set-up is complete, users can listen with the HAF using the AirPods Pro and refine their settings. Fine tuning is facilitated by user controls on the iOS device that can adjust amplification, tone, and balance. A user can access the fine tuning settings at any time after setting up the HAF.

The HAF settings are transferred to the HAF Firmware Module on the AirPods Pro. The HAF Firmware Module utilizes the general purpose computing platform features of the AirPods Pro, including the microphone, speakers, amplifiers, and audio processing software, to process incoming sound and provide amplification at a specific frequency and gain based on the user's custom settings. The user's custom settings are stored on the HAF Firmware Module and will be available even when the AirPods Pro are not connected to the iOS device.

Multiple Function Device Products

This product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. Specifically, the Apple AirPods Pro and iOS products host numerous other functions for non-medical, general wellness and/or general consumer purposes. Consistent with FDA's guidance titled, "Multiple Function Device Products: Policy and Considerations," FDA assessed the other functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review. Specifically, while the AirPods Pro product contains other known and unknown audio functions, the device function under review was the HAF. The assessment concluded that the identified risks posed by the other known functions, aside from those functions that directly enable HAF functionality (e.g., microphone, speakers, amplifiers, core audio processing, etc.), are minimal and do not impact the safety or effectiveness of the device.

[1] The sponsor considers that HealthKit is a Non-Device Medical Device Data System per the FDA guidance at the following link: https://www.fda.gov/media/88572/download.
[2] The Apple Hearing Test Feature is a separate medical device registered under product code 'EWO'.

SUMMARY OF NONCLINICAL/BENCH STUDIES

SOFTWARE

The software documentation provided in the De Novo request is consistent with the intended use of the device and recommendations identified according to FDA Guidance Document *Content of Premarket Submissions for Device Software Functions* (issued June 14, 2023) and *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (issued September 27, 2023):

- Documentation Level Rationale
- Software Description
- Risk Management File
- Software Requirements Specification (SRS)
- System and Software Architecture
- Software Design Specification (SDS)
- Software Testing as part of Verification and Validation
- Software Version History
- Unresolved Anomalies
- Cybersecurity

The device also conforms to the cybersecurity requirements identified in Section 524B of the FD&C Act.

An overview of the device software and non-device software features are outlined in the software documentation. A comprehensive risk analysis is provided with detailed description of the hazards, their causes, severity and probability of occurrence, as well as risk control measures for the identified hazards. Additional software and bench performance-testing verification is summarized below.

PERFORMANCE TESTING - BENCH

The verification and validation activities demonstrate that the HAF meets all predetermined acceptance criteria including the performance requirements outlined in 21 CFR 800.30. Compliance to the electroacoustic performance testing requirements of 21 CFR 800.30 (parts (d) and (e)) are outlined below in Table 1.

Table 1. HAF software with required product(s): 800.30(d) & (e) compliance.

	CFR Requirement	Compliance
Output Limits (21 CFR 800.30(d))	**1) General output limit. An OTC hearing aid shall not exceed an output limit of 111 dB SPL at any frequency except as provided in paragraph (d)(2) of this section**	N/A - This requirement is not applicable as the subject device is an input-controlled compression device and are applying the 117 dB SPL limit specified in part (2) below.
	2) Output limit for a device with activated input-controlled compression. An OTC hearing aid that has input-controlled compression activated shall not exceed an output limit of 117 dB SPL at any frequency.	Max OSPL90: 105.93 dB SPL
Electroacoustic performance limits (21 CFR 800.30 (e))	**1) Output distortion control limits. The total harmonic distortion plus noise shall not exceed 5 percent for output levels.**	Harmonic distortion does not exceed 1% for any test frequency at the following input levels as specified in applicable ANSI/ASA S3.22 or ANSI/CTA 2051:2017 clauses: - 500Hz, 800Hz @ 70dBSPL - 1.6kHz @ 65dBSPL - 500Hz @ 100 dBSPL
	2) Self-generated noise level limits. Self-generated noise shall not exceed 32 dBA.	Max Self-Generated Noise: 28.20 dBA
	3) Latency. Latency shall not exceed 15 ms.	Median Latency: 3.15 ms
	4) Frequency response bandwidth. The lower cutoff frequency shall extend to 250 Hz or below, and the upper cutoff frequency shall extend to 5 kHz or greater.	Per Clause 4.1 in ANSI/CTA-2051:2017, the frequency bandwidth is: 100 - 10,000 Hz
	5) Frequency response smoothness. No single peak in the one-third-octave frequency response shall exceed 12 dB relative to the average levels of the one-third-octave bands, two-thirds octave above and below the peak.	Per Clause 4.1 in ANSI/CTA-2051:2017, all peaks <12dB relative to adjacent bands (two above, two below), are within the frequency response bandwidth.
	6) Acoustic coupler choice. When compatible with the device design, a 2-cubic centimeter (cm^3) acoustic coupler	2 cm^3 acoustic coupler used.
Design requirements (21 CFR 800.30 (f))	**1) Insertion depth. The design of an OTC hearing aid shall limit the insertion of the most medial component so that, when inserted, the component is reasonably expected to remain at least 10**	>10mm gap from tympanic membrane. Verified via multiple ear tip sizes, instructions and usability testing for AirPods Pro platform.

	CFR Requirement	Compliance
	millimeters (mm) from the tympanic membrane.	
	2) Use of atraumatic materials.	AirPods Pro platform has been verified to use atraumatic patient contacting materials.
	3) Proper physical fit.	Even though the HAF is a software-only device, this requirement has been met for the AirPods Pro platform used with HAF. Refer to the insertion depth compliance information above.
	4) Tools, tests, or software. The OTC hearing aid shall, through tools, tests, or software, permit a lay user to control the device and customize it to the user's hearing needs.	HAF fitting is customized based on input audiogram processing. Afterward, the HAF contains three fine-tuning sliders (amplification, tone, balance) for the user to customize the hearing aid to their needs.
	5) User-adjustable volume control. The OTC hearing aid shall have a user-adjustable volume control.	The HAF has an amplification fine-tuning slider to adjust the volume.
	6) Adequate reprocessing.	Even though the HAF is a software-only device, the adequacy of the reprocessing of the compatible AirPods Pro platform has been verified via the instructions and design mitigations.

Human Factors and Usability Studies

Human Factors formative testing with 39 subjects was conducted to assess the use-related risks associated with use of the HAF. Documentation on the intended device users, uses, use environments, and training was developed as part of the process along with a Use-Related Risk Analysis (URRA). The URRA was conducted to assess any critical tasks and any potential use errors associated with the HAF. The intended users in the study were adults aged 18 or older with perceived mild to moderate hearing loss, which is aligned with the proposed indications for use. Participants enrolled in the formative testing varied in age, education level, and in their prior hearing aid use experience; no demographic inclusion criteria aside from age range were pre-specified. The test environment was designed to represent the user's typical everyday environment with no training provided to the users prior to evaluation. This is reflective of how the user would interact with the device in a real-world setting. The results of this human factors testing demonstrate that all use-related risks have been reduced as far as possible following the implementation of any software design modifications based on the findings.

In addition to the above formative usability testing and design-based modifications for HAF, an additional formative study and analysis was also conducted to identify risks and mitigations for audiogram input to HAF (via the Hearing Test Feature or third-party audiogram import to the HealthKit). Risks and mitigations for audiogram input (both Hearing Test Feature generated or imported) to HAF from HealthKit have been identified and addressed through a combination of design, verification and validation of Hearing Test Feature, HAF, and HealthKit, together with supporting labeling, including HAF Instructions for Use with troubleshooting information (e.g.

fine-tuning, selecting correct ear tip size) and general AirPods Pro instructions for how to properly select an ear tip size and appropriately place the AirPods Pro in ear.

Electrical and Battery Safety, Electromagnetic Compatibility & Wireless Coexistence/Safety
A consumer electronic device, AirPods Pro were verified to comply with the following standard: Safety of Audio/Video, Information, and Communication Technology Equipment (IEC 62368-1). Additionally, applicable clauses in IEC 60601-1-2 and IEC 60601-1 have been assessed to further demonstrate the safety of the AirPods Pro. The following clauses of IEC 60601-1 and IEC 60601-1-2 have been evaluated and found to be acceptable, providing additional assurance of safety of the AirPods Pro with the applicable RF and EMC emission and immunity, thermal safety, and battery safety guidelines:

- IEC 60601-1-2
  - Radiated Emissions (CISPR 11 Class B)
  - Conducted Emissions (CISPR 11 Class B)
  - Electrostatic Discharge (IEC 61000-4-2)
  - Radiated Frequency Immunity (IEC 61000-4-3)
  - Electric Fast Transients (IEC 61000-4-4)
  - Surge (IEC 61000-4-5)
  - RF Common Mode Immunity (IEC 61000-4-6)
  - Power Frequency Magnetic Field (IEC 61000-4-8)
  - Voltage Dips/Interruptions (IEC 61000-4-11)
  - Proximity Magnetic Field (IEC 61000-4-39)
- IEC 60601-1
  - Power Input (Clause 4.11)
  - Durability of Markings (Clause 7.1.2)
  - Leakage Current Test (Clause 8.7)
  - Temperature Test (Clause 11.1)
  - IP Test (Clause 11.65)
  - Interruption of Power Supply (Clause 11.8)
  - Single Fault Condition Test (Clause 13.2)
  - Push Test (Clause 15.3.2)
  - Impact Test (Clause 15.3.3)
  - Molding Stress Relief Test (Clause 15.3.6)
  - Battery Tests (Clause 15.4.3)

The range of testing and all acceptance criteria are appropriate to evaluate this device based on its proposed intended use. All acceptance criteria were met. The compatible AirPods Pro products have been evaluated to demonstrate compliance with the applicable RF and EMC emission and immunity, thermal safety, and battery safety guidelines. This testing/analysis, together with the existing vast post-market evidence of safe consumer use, provides acceptable assurance of the safety of the AirPods Pro platform to support use with the HAF.

SUMMARY OF CLINICAL INFORMATION

Clinical evidence for the HAF's safety and effectiveness was established in a prospective, non-

significant risk study from three sites across the United States with 118 (total) participants. The study enrolled subjects across the spectrum of hearing loss classifications, with a broad distribution across each of the following categories per the WHO 1991 4PTA classification[3]: No Hearing Impairment (15 – 25 dB HL and perceived hearing loss), Mild Hearing Loss (26 – 40 dB HL), and Moderate Hearing Loss (41 – 60 dB HL). Current regular users of hearing aids were excluded from participating in the study. Subjects were also enrolled based on demographic factors of age (less than or greater than 60 years old) and sex, to represent the intended patient population.

The primary purpose of the study was to evaluate the performance of the HAF Self-Fit (SF) formula against using the National Acoustic Laboratories Nonlinear 2nd edition (NAL-NL2) fitting formula that was Professionally-Fit (PF) by an audiologist. Subjects in both the SF and PF groups used the Apple AirPods Pro as the wearable hardware platform. Professionally derived audiogram inputs were measured and used for the hearing-aid fittings for both groups. The primary outcome measure of the study was the International Outcome Inventory for Hearing Aids (IOI-HA)[4].

Users were evaluated over a 31-day period, which included three clinic visits interspersed with two home-interval periods. The PF group had their hearing aids fitted by the audiologist at the first clinic visit while the second clinical visit comprised an optional, audiologist fine-tuning session. Users in this PF group could also fine-tune their amplification settings during the second home-interval period. The SF group had initial tuning automatically completed by the HAF at the first clinic visit; SF users could then adjust amplification, tone, and balance whenever needed, both during clinic visits and home-interval periods. During the home-interval periods, subjects in both groups were encouraged to use the devices during their daily activities and in their routine environments. There was a prespecified minimum expected daily wear and use time, i.e., use duration, of at least 30 minutes per day (100% of subjects across both the SF and PF groups met and exceeded this duration). Table 2 shows the demographics of the study users. Table 3 summarizes the SF vs. PF group IOA-HA results.

[3] Olusanya BO, Davis AC, Hoffman HJ. Hearing loss grades and the International classification of functioning, disability and health. Bull World Health Organ. 2019 Oct 1;97(10):725-728. doi:10.2471/BLT.19.230367.
[4] Cox, R.M., and Alexander, G.C. "The International Outcome Inventory for Hearing Aids (IOI-HA): psychometric properties of the English version." International Journal of Aud. 41(1): 30-35 (2002). https://doi.org/10.3109/14992020209101309

Table 2: Clinical study user demographics.

Characteristics	Self-Fit (n=59)	Pro-Fit (n=59)
Age		
Mean	57.9	60.4
Std. Dev	16.05	11.83
Median	62.0	62.0
Min – Max	22 – 85	25 – 79
Age Group		
<60	25 (42.4%)	25 (42.4%)
≥60	34 (57.6%)	34 (57.6%)
Sex		
Male	29 (49.2%)	20 (33.9%)
Female	30 (50.8%)	39 (66.1%)
Ethnicity		
Hispanic or Latino	1 (1.7%)	1 (1.7%)
Not Hispanic or Latino	58 (98.3%)	58 (98.3%)
Race		
Asian	1 (1.7%)	0 (0.00%)
Black or African American	4 (6.8%)	10 (16.9%)
White	53 (89.8%)	48 (81.4%)
More than One Race	0 (0.0%)	1 (1.7%)
Not Reported	1 (1.7%)	0 (0.0%)

Table 3: IOI-HA Scores for Self-Fit and Pro-Fit groups for two study data sets.

Analysis Set	Mean (SD) IOI-HA Score		Mean Difference (SD) Pro-Fit – Self-Fit	95% Confidence Interval for Mean Difference	Non-Inferiority Margin	P-Value	Conclusion
	Self-Fit N = 59	Pro-Fit N=59*					
FAS/CCAS	25.5 (3.03)	26.6 (3.63)	1.17 (3.34)	(-0.05, 2.39)	3.0	0.0036	Pass
PP	25.5 (3.03)	26.7 (3.63)	1.23 (3.34)	(0.01, 2.46)	3.0	0.0050	Pass

*N=58 in Pro-Fit Group for Per Protocol Analysis (One subject removed due to being incorrectly enrolled without meeting all inclusion/exclusion criteria)

The primary endpoint assessed the IOI-HA difference in scores between the SF and PF group across the entire study population. Study success was defined as a SF-group mean-score that was no more than 3 points below the PF-group mean-score, i.e., the non-inferiority margin. Table 3 demonstrates that users fit by the automatic HAF fitting-algorithm achieved the same perceived benefit compared with users with hearing aid settings tuned by a professional audiologist. Moreover, subgroup analyses indicated that the IOI-HA scores were consistent for both the SF

and PF groups across hearing classification, age, sex, and race.

Of note, there was a statistically significant unexplained variability in the primary endpoint across the three study sites, unattributed to any key demographic imbalances (e.g. Age, Sex, Race, Hearing Impairment classification, AirPods Wear Time, otoscopy results, etc.). Thus, individual site results were examined. The mean IOI-HA score for the SF group was about 1.5 points greater at the largest site (n=49) and about 3 points less at the other two sites (n = 33 and 20, respectively) , as compared to the PF group. This performance difference is not considered clinically significant.

Additional objective measures (Speech-in-Noise (QuickSIN) and Real Ear Measure (REM)) were also collected to assess objective changes in amplification between the SF and PF groups. QuickSIN results demonstrate that there was no difference in speech intelligibility performance between the SF and PF group. In line with the finding of non-inferior IOI-HA scores between the SF and PF groups, REM (gain) results demonstrated no substantive differences in gain (> 5dB) trends across frequency at 50, 65, and 80 dB SPL, respectively. See Table 4 for 65 dB SPL results.

Table 4. Real Ear Measure Gain (SD) in dB at 65 dB SPL.

Input Level (dB SPL)	**65 dB SPL**							
Frequency (kHz)	**0.25**	**0.5**	**1**	**2**	**3**	**4**	**6**	**8**
SF (N=59)	4.7 (3.5)	5.2 (3.3)	7.6 (3.8)	5.3 (3.5)	4.9 (3.8)	9.2 (4.6)	7.4 (5.1)	9.1 (5.2)
PF (N=59)	3.9 (3.1)	3.6 (2.9)	4.0 (3.2)	2.6 (2.1)	2.5 (1.8)	4.5 (3.5)	4.9 (4.1)	6.9 (4.8)

In terms of study safety, one subject (1/118, 0.8% of total subjects) experienced two non-device related adverse events, this subject was in the PF group.

Supplemental Clinical Data: Apple Hearing Test Feature Validation

Audiogram input is required for HAF. The HAF is accompanied by the Hearing Test Feature (HTF), a separate Class II Exempt device registered under 21 CFR 874.1050. HTF can be used to generate an audiogram to be used with HAF. A validation study of HTF was conducted by (1) comparing HTF outputs to professionally derived audiograms, and (2) comparing gain profiles of HAF for HTF derived audiograms vs. professionally derived audiograms. One dataset (n = 202) demonstrated a similar pure-tone average for HTF derived audiograms as professionally derived audiograms (for the same users). Furthermore, for a subset of these subjects with mild to moderate hearing loss (n=173), a gain analysis was conducted to determine if the gain values generated by HAF were similar for HTF vs. professionally-derived audiograms. The output gains across all test frequencies were within +/- 5 dB for >98% of gain differences (meeting the pre-specified acceptance criteria of +/- 5 dB for 90% of gain differences).

Pediatric Extrapolation

The Hearing Aid Feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. For medical devices, the Federal Food, Drug, and Cosmetic Act defines patients before their 22nd birthday as pediatric patients. In this De Novo request, existing clinical data were not leveraged to support the use of the device in individuals younger than 18 years old. It was appropriate to indicate the device for individuals 18 and older because patients aged 18 to 21 do not carry additional differences or risks relative to the patient population studied.

PREDETERMINED CHANGE CONTROL PLAN

The submission contains a Predetermined Change Control Plan (PCCP), which complies with Section 3308 of the Food and Drug Omnibus Reform Act (FDORA) of 2022, enacted on December 29, 2022. The PCCP contains planned modifications to the output gain of the HAF intended to improve a user's overall listening experience as well as to provide additional benefit to users. The planned modifications to the output gain include changes to the maximum allowable gain limit, expanded frequency bandwidth, and the addition of environment-specific programs with modified gain output settings. Acceptable modification limits for each change have been provided.

The PCCP includes a modification protocol describing the verification and validation activities that will support the proposed changes. The proposed changes will undergo software verification testing to ensure that all new and existing requirements are still met. Additionally, performance validation testing will be conducted to establish substantial equivalence to the authorized version of the HAF. Specific test protocols, including methods of implementation and acceptance criteria, provide sufficient means to implement the outlined modifications without requiring an additional marketing submission prior to implementation. PCCP revisions of the HAF are version controlled and documented based on the design control requirements.

A procedure for Instructions for Use updates has also been established in order to inform users about changes implemented under this FDA authorized PCCP. Apple will verify the applicable changes, the associated version of the device, the availability and compatibility of the feature, and the device performance. Apple will publish updated Instructions for Use on its website, and make them accessible within the Health App.

LABELING

The labeling for the device is sufficient and satisfies the applicable requirements of 21 CFR 800.30. The labeling consists of Instructions for Use and an onboarding sequence. The Instructions for Use include the indications for use; a description of the device; precautions and warnings; a detailed summary of the clinical data collected in support of the device; a list of probable adverse events; and instructions for the safe use of the device.

Please see the Limitations section above for important contraindications, warnings and precautions presented in the device labeling.

RISKS TO HEALTH

Table 5 identifies the risks to health that may be associated with air-conduction hearing aid software and the measures necessary to mitigate these risks.

Table 5. Identified Risks to Health and Mitigation Measures

Risks to Health	Mitigation Measures
Physical discomfort or worsening hearing due to providing higher than desired output	Clinical performance data Non-clinical performance testing Software verification, validation, and hazard analysis Design verification and validation Labeling
Insufficient sound amplification leading to ineffective treatment and poorer than expected patient outcomes	Clinical performance data Non-clinical performance testing Software verification, validation, and hazard analysis Design verification and validation Labeling
Missed or delayed or incorrect medical treatment due to poor design/use error or device misuse	Clinical performance data Non-clinical performance testing Usability data Software verification, validation, and hazard analysis Design verification and validation Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, including 21 CFR 800.30 (over-the-counter hearing aids) and 21 CFR 801.422 (prescription hearing aids) as applicable, air-conduction hearing aid software is subject to the following special controls:

(1) Performance data must validate the customization strategy of the hearing aid software with representative, compatible hardware. Self-fitting strategies must be validated with clinical performance data.

(2) Non-clinical performance testing with representative, compatible hardware must verify that the amplified acoustic signal outputted by the hardware platform is calibrated.

(3) Usability data must demonstrate that the intended user can correctly operate the hearing aid based solely on reading the directions for use, including setup and use with representative, compatible hardware.

(4) Software verification, validation, and hazard analysis must be performed. Documentation must include:

(i) Characterization of the technical specifications of the software, including the user customization and amplification algorithms, inputs and outputs, and all relevant software components;
(ii) Minimum requirements for compatible hardware and software platform(s) to ensure the software device functions as intended;
(iii) A description of all mitigations for failure of any software subsystem components, including sound transduction, signal processing, and hearing loss compensation; and
(iv) A description of all interactions with other audio functionality on the hardware platform.

(5) For devices with a predetermined change control plan (PCCP), documentation must include the planned modifications to the device, the risks of the planned modifications and corresponding risk mitigations, and the verification and validation activities, including pre-specified acceptance criteria, that will be performed for specified device modifications.

(6) Labeling must include the following:
(i) Labeling required by § 800.30 or § 801.422 of this chapter, as applicable, including compatible hardware and software platforms by model and/or specification; and
(ii) For devices with a PCCP, labeling related to the PCCP, including:
(A) A statement that the device has a PCCP;
(B) A description of planned modification(s) to the device, including validation requirements; and
(C) A version history, a description of how device modification(s) will be implemented, and a description of how users will be informed of device modification(s) made in accordance with the PCCP.

BENEFIT/RISK DETERMINATION

The probable benefits of the HAF have been established through assessment of data derived from the clinical validation study results summarized above, which evaluated 118 subjects. The clinical validation study, using professionally-derived audiogram inputs, demonstrate that subjects who used the HAF Self-Fit formula achieved the same perceived benefit (IOI-HA score comprising seven domains including use, benefit, satisfaction, quality of life, etc.) as subjects who were professionally-fit by an audiologist using a standard clinical hearing aid fitting formula. The same hardware platform AirPods Pro were used as a control for both the SF and PF groups. The HAF met the primary effectiveness endpoint with the subgroup analysis showing that performance of the SF group was consistent with the PF group across all questions of the IOI- HA survey, regardless of hearing classification, age, sex, and race. The results from the exploratory endpoints of Speech-in-Noise (QuickSIN) and Real Ear Measures (REM) show that there was no difference in speech intelligibility performance between SF and PF groups, while the SF group tended to prefer slightly less gain.

The HAF has a low-to-moderate risk profile as defined in the risk assessment. The probable risks include physical discomfort or worsening hearing due to providing higher than desired output, insufficient sound amplification leading to ineffective treatment and poorer than expected patient outcomes, and missed or delayed or incorrect medical treatment due to poor design/use error or device misuse. Furthermore, there are significant risk mitigation controls in place to reduce all risks to an acceptable level. Finally, the clinical validation study results demonstrated that the HAF has a robust safety profile with only one subject (1/118, 0.8% of total subjects) experiencing two non-device related adverse events in the PF group. Overall, the HAF raised no safety concerns across a broad demographic range of patients with perceived or measured mild to moderate hearing loss. The safety profile of the HAF presents minimal risk to the user and is as safe as traditional hearing aid devices.

In summary, the totality of the evidence, including the clinical validation, supplemental clinical information, non-clinical software testing, other non-clinical testing (including 21 CFR 800.30 compliance), human factors testing, and established risk mitigation measures, support that the benefits outweigh the risks and low uncertainty associated with the HAF.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, the data support that for the indications for use statement:

> 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-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.

The probable benefits outweigh the probable risks for the Hearing Aid Feature. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Hearing Aid Feature is granted and the device is classified under the following:

Product Code: SCR
Device Type: Air-conduction hearing aid software
Class: II
Regulation: 21 CFR 874.3335