September 12, 2024

Apple Inc.
Kevin Go
Principal Regulatory Affairs Specialist
One Apple Park Way
Cupertino, California 95014

Re: DEN230081
Trade/Device Name: Hearing Aid Feature (HAF)
Regulation Number: 21 CFR 874.3335
Regulation Name: Air-conduction hearing aid software
Regulatory Class: Class II
Product Code: SCR
Dated: December 4, 2023
Received: December 4, 2023

Dear Kevin Go:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Hearing Aid Feature (HAF), an over-the-counter device under 21 CFR Part 801 Subpart C with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Hearing Aid Feature (HAF), and substantially equivalent devices of this generic type, into Class II under the generic name air-conduction hearing aid software.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 4, 2023, FDA received your De Novo requesting classification of the Hearing Aid Feature (HAF). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Hearing Aid Feature (HAF) into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Hearing Aid Feature (HAF) can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type.

The identified risks and mitigation measures associated with the device type are summarized in the following table:

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

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, the 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.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

FDA's granting of your De Novo request also included the review and authorization of your Predetermined Change Control Plan (PCCP) titled "HEARING AID FEATURE (HAF) PREDETERMINED CHANGE CONTROL PLAN (PCCP)" (received July 1, 2024). Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the authorized PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the air-conduction hearing aid software they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Vasant Dasika, Ph.D. at 301-796-5365.

Sincerely,

FDA Malvina B. Eydelman -S
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Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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