July 31, 2026

Samsung Electronics Co., Ltd.
% Chaoyi Kang
Lead Biomedical Engineer
Samsung Research America, Inc.
665 Clyde Ave.
Mountain View, California 94043

Re: K261187
Trade/Device Name: Hearing Aid Feature
Regulation Number: 21 CFR 874.3335
Regulation Name: Air-Conduction Hearing Aid Software
Regulatory Class: Class II
Product Code: SCR
Dated: July 1, 2026
Received: July 1, 2026

Dear Chaoyi Kang:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. 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 established 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 section 515C(b)(1) of the Act and 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.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K261187

Device Name
Hearing Aid Feature

Indications for Use *(Describe)*
The Samsung Hearing Aid is an over-the-counter (OTC) software-only, mobile medical application intended to amplify sound for users 18 years or older with perceived mild-to moderate hearing impairment.

The device operates on compatible Samsung Galaxy mobile and earbud wearable devices, both off-the-shelf commercial platforms. The user is intended to self-fit the device, including adjusting it to suit their own hearing needs, without assistance from a hearing healthcare professional.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Samsung Hearing Aid Feature
510(k) Summary

Applicant Information

Manufacturer:	**Samsung Electronics Co., Ltd** 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do 16677, Korea
Contact Person:	**Chaoyi Kang, Ph.D.** Samsung Research America 665 Clyde Avenue, Mountain View, CA 94043 1-650-305-9330 chaoyi.kang@samsung.com
Date Prepared:	April 10th, 2026

Device Information

Trade/Device Name:	Hearing Aid Feature
Classification:	• SCR – air-conduction hearing aid software (21 CFR 874.3335)
Predicate Device:	• Hearing Aid Feature (DEN230081)

Device Description

The Samsung Hearing Aid Feature (HAF) is an over-the-counter, software as a medical device (SaMD) that includes a pair of medical software applications: one on the Samsung Galaxy earbuds (e.g., Galaxy Buds3 Pro) and the other on the Samsung Galaxy mobile device (e.g., Samsung Galaxy S23), both off-the-shelf computing platforms. The SaMD on the mobile platform will provide the user with user interfaces (UIs), onboarding, self-fitting procedure, configuration/settings, safety information and instructions to meet the user's hearing needs. The SaMD on the hearable platform will provide audio processing, amplification, and output the amplified sound to the user through the earbuds.

Samsung HAF provides a self-fitting strategy for the user to set up their hearing aid amplification profile. HAF allows the user to import hearing loss thresholds from an audiogram and uses the widely used NAL-NL2 (the second generation of prescription procedures from the National Acoustic Laboratories for fitting non-linear hearing aids) algorithm to automatically fit the amplification to the user's hearing needs. Additional controls, such as volume tuning and beamforming, are provided to the user to fit the variety of user needs for different daily scenarios.

Indications for Use

The Samsung Hearing Aid Feature is indicated as follows:

> *The Samsung Hearing Aid is an over-the-counter (OTC) software-only, mobile medical application intended to amplify sound for users 18 years or older with perceived mild-to-moderate hearing impairment.*
>
> *The device operates on compatible Samsung Galaxy mobile and earbud wearable devices, both off-the-shelf commercial platforms. The user is intended to self-fit the device, including adjusting it to suit their own hearing needs, without assistance from a hearing healthcare professional.*

Comparison of Technological Characteristics

The subject Samsung Hearing Aid Feature and the predicate device (DEN230081) have similar intended use, technological characteristics, and principles of operation. The slight differences in indications for use wording does not represent a new intended use. Both the subject and predicate devices are software-only mobile medical applications intended to amplify sound for individuals with perceived mild to moderate hearing impairment.

A more detailed comparison between the subject device and the predicate device (Apple Hearing Aid Feature, DEN230081) is provided in ***Table 1***.

Table 1. Technological Comparison of Subject Device and Predicate Device

Characteristic	Subject Device: Samsung Hearing Aid Feature	Predicate Device: Apple Hearing Aid Feature (HAF) DEN230081	Comparison
Indications for Use	The Samsung Hearing Aid Feature is an over-the-counter (OTC) software-only, mobile medical application intended to amplify sound for users 18 years or older with perceived mild-to-moderate hearing impairment. The device operates on compatible Samsung Galaxy mobile and earbud wearable devices, both off-the-shelf commercial platforms. The user is intended to use the device, including adjusting it to suit their own hearing needs, without assistance from a hearing healthcare professional.	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 indications for use of the subject device are substantially equivalent to the predicate.
Fit Type	Self-fitting – The user creates a hearing profile through the Samsung Hearing Test Feature then adjusts amplification and tuning through a guided self-fitting in Samsung Hearing Aid Feature.	Self-fitting – The user adjusts amplification and tuning through a guided self-fitting process using iOS Health app hearing test data.	Substantially equivalent to the predicate device. Clinical and acoustic performance testing evaluated these differences in technology and the results support substantial equivalence.
Platform	**OS Platform** • Android **Amplification Platform** • Adjustable Ear Tips • On Device Controls • Selectable directional Microphone • Rechargeable Battery • Earbuds Charging Case • Receiver-in-Canal (RIC)	**OS Platform** • iOS **Amplification Platform** • Adjustable Ear Tips • On Device Controls • Selectable directional Microphone • Rechargeable Battery • Earbuds Charging Case • Receiver-in-Canal (RIC)	While the subject and predicate devices use different operating platforms, they are substantially equivalent. Feature set of the amplification platform (Buds) are also substantially equivalent.

Characteristic	Subject Device: Samsung Hearing Aid Feature	Predicate Device: Apple Hearing Aid Feature (HAF) DEN230081	Comparison
Acoustic Performance	• Max OSPL90: 111.9 dB SPL (with activated input-controlled compression) • Full-on Gain (FOG): 31.5 dB • Frequency Response bandwidth: 100 – 9030 Hz • Total Harmonic Distortion: ≤1% for all applicable test frequencies • Input Noise (EIN): 24.9 dB • Latency: 2.7 ms	• Max OSPL90: 106 dB SPL • Full-on Gain (FOG): 31.5 dB • Frequency Response bandwidth: 100 – 10,000 Hz • Total Harmonic Distortion: ≤1% for any applicable test frequencies • Input Noise: 27 dB • Latency: 3.15 ms	All acoustic characteristics of the subject device comply with 21 CFR800.30 – Over-the-Counter Hearing Aid Controls. Most acoustic characteristics are substantially equivalent to the predicate device, the difference in Max OSPL90 was evaluated in the clinical performance testing and the results also supports substantial equivalence.
Clinical Performance	APHAB Global Benefits of Self-Fit Group is non-inferior to the Clinician-Fit group Mean Difference of -1.01 (95% UCB of 5.81)	IOI-HA Survey Score of Self-Fit Group is non-inferior to the Clinician-Fit group Mean Difference of 1.17 (95% CI of -0.05; 2.39)	Subject device uses a different but well accepted questionnaire to evaluate non-inferiority in perceived benefit. Both studies demonstrated non-inferiority of the self-fitting strategy, therefore the subject device have substantially equivalent clinical performance compared to the predicate device.

Performance Data Summary

The following clinical, usability, and bench testing were conducted, showing that the subject SaMD demonstrates safety, effectiveness, and substantial equivalence to the predicate device. No new safety issues were found during this testing.

- Clinical Validation showing comparable clinical performance in terms of non-inferiority of self-fitting compared to clinician fitting for the following metrics:
  - Subject-level perceived benefit of improvement
  - Real Ear Achieved Gain
  - Speech-in-Noise
- Human Factors Validation demonstrating:
  - All participants were able to onboard and use the feature without any use errors that could result in a clinical harm.
- SaMD Bench Testing for
  - Wide Dynamic Range Compression
  - Feedback Cancellation
  - Beamforming
  - Noise Suppression
- Software Verification Testing
- Labeling Verification Testing

In addition, testing was performed on the commercial platform, showing it meets all necessary specifications to safely and effectively host the subject SaMD. This included the following:

- Acoustic Testing
- Platform Interface Software Testing (Android and WearOS)
- Platform Interface Hardware Testing for General Safety
  - Device Electrical Safety
    - IEC 62368-1:2014 + A11:2017 - Electronics device safety including "Touch temperature limits" and battery safety.
    - IEC 60068-2-78 – High Temperature and Humidity Test
    - IEC 60068-2-1, IEC 60068-2-2 – Temperature Operation Test
    - IEC 60068-2-14 – Thermal Shock Test
    - IEC 60068-2-38 – Accelerated Life Test
  - Electromagnetic Compatibility
    - EN 55032:2015 – Conducted and Radiated Emissions
    - EN 61000-4-2:2009 – Electrostatic Discharge
    - EN 61000-4-3: 2006 +A1:2008 +A2:2010 – Radiated Immunity
    - EN 61000-4-4: 2012 – Electrical Fast Transient/Burst
    - EN 61000-4-5: 2014 +A1:2017 – Surge Immunity
    - EN 61000-4-6: 2014 – Conducted Immunity
    - EN 61000-4-11: 2004 – Voltage dips and Interruptions
  - Material Safety for cytotoxicity, skin sensitization, skin exposure
    - ISO10993-23 Animal irritation test by skin exposure

        - ISO10993-5 Tests for in vitro Cytotoxicity
        - ISO10993-10 Tests for irritation and skin sensitization
    - Thermal Safety for skin contact
- Additional Platform Interface Hardware Testing for Device Robustness
    - Water Ingress
        - IEC 60529:2013 – Ingress of protection provided by enclosure (IPX7: 14.2.7 Test for second characteristic numeral 7)
    - Breakage Resistance

Furthermore, Samsung's cybersecurity process for device development adheres to FDA's 2026 Guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Human Factors Study

The Samsung Hearing Aid Feature (HAF) underwent a thorough Human Factors process, which followed the guidelines provided in the FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff (2016).

A Use-Related Risk Analysis (URRA) was conducted to identify potential use errors and critical tasks associated with the HAF. Ten (10) formative tests were conducted to identify and assess use-related risks and guide the user interface design, mitigations, and labeling. Studies included intended users of the device who were 18 years or older with perceived mild to moderate hearing loss. Participants varied in age and education levels and included a subset of older adults, new users of hearing aid technology, new users of wireless earbuds, and non-Samsung device users. The studies were conducted using simulated use and interview methods. To reflect real-world interactions with the device, no training was provided to the users prior to the evaluation.

The Human Factors (HF) Validation study demonstrates that users understand how to appropriately use the device, and that use-related risks are effectively mitigated through the design of the user interface and labeling materials. As an existing audiogram from the Hearing Test Feature is required to set up the HAF, a total of 31 recruited participants took a hearing test using the Samsung Hearing Test Feature. Fifteen (15) participants with perceived mild-to-moderate hearing loss went on to set up and use the HAF. In the study, no use errors were found that could result in clinical harm, therefore supporting the conclusion that the HAF can be used safely and effectively by the intended users, for the intended uses, and in the intended use environments.

Clinical Study

The Samsung Hearing Aid Feature was validated in a prospective, multi-center study conducted over an approximately 30-day period in adults 18 years or older with mild-to-moderate hearing loss.

The study evaluated the user-perceived benefit, per the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire, between participants who were Self-Fit (SF), using the Samsung Hearing Aid Feature with audiogram generated by Samsung Hearing Test Feature,

and participants who were fitted by a clinical audiologist (CF) using the National Acoustic Laboratories Nonlinear, Second Edition (NAL-NL2) fitting procedure.

A total of 103 participants were enrolled across the mild-to-moderate range of hearing loss, per the hearing loss degrees recognized by the American Speech–Language–Hearing Association (ASHA). Enrollment included predefined demographic targets for age, sex, and previous hearing aid experience to ensure representation of the intended user population.

In the study, the average APHAB Global benefit scores were 16.59 (σ=21.91) for the SF cohort and 15.59 (σ=16.52) for the CF cohort. The mean difference between cohorts (CF – SF) was -1.01 (95% upper confidence bound=5.81), which was successfully below the study criteria's non-inferiority margin of 9.9. Statistically, the mean APHAB Global benefit score of the SF cohort was proven non-inferior to that of the CF cohort with a p-value of 0.0046. Therefore, users who self-fit using the Samsung Hearing Aid Feature were able to achieve a similar perceived benefit compared with users fit by a clinical audiologist. Further subgroup analysis indicated that the CF-SF scores were consistent across age, sex, race, and hearing ability.

Additional quantitative measures included speech intelligibility and achieved amplification. Speech intelligibility was assessed using the Quick Speech-in-Noise (QuickSIN) test and showed no meaningful differences between the SF and CF cohorts, while Real Ear Measurement (REM) testing demonstrated similar gain trends between the SF and CF cohorts across input levels of 50-, 65-, and 80-dB SPL.

No device-related or study-related adverse events were reported. As the Self-Fit group of Hearing Aid Clinical Validation uses audiogram generated by the Samsung Hearing Test Feature, this clinical validation with supplemental Hearing Test performance detailed below demonstrated that Samsung Hearing Aid Feature using input from Samsung Hearing Test meets the clinical performance validation special control per 21 CFR 874.3335.

Supplemental Performance Data

Audiogram input is required for the Samsung Hearing Aid Feature, which the users can obtain by using a separate, Class II exempt device, the Samsung Hearing Test Feature. A clinical validation study was conducted for the Samsung Hearing Test Feature, where the device measured hearing loss thresholds were compare against the gold standard, audiogram from the clinical Pure Tone Audiometry performed by a clinical audiologist. The primary endpoint analysis in 367 participants demonstrated that audiogram produced by Samsung Hearing Test is accurate with a median absolute difference of 3.75 dB. Furthermore, no significant performance discrepancy was observed across demographic subgroups of age, sex, race, and hearing ability.

Predetermined Change Control Plan (PCCP)

The Samsung Hearing Aid Feature contains a Predetermined Change Control Plan (PCCP), which complies with Section 3308 of the Food and Drug Omnibus Reform Act (FDORA) of 2022. The PCCP includes a list of the allowable device software modifications and protocols describing the verification activities that will support the proposed changes (see ***Table 2***). All changes will be sufficiently bounded in terms of associated parameters to support safety and effectiveness of the device, and that substantial equivalence is not negatively affected.

The modification protocol incorporates impact assessment considerations and specifies requirements for data management, including data sources, collection, storage, and sequestration, as well as documentation and data re-use practices. Specific test methods are specified in the PCCP to establish substantial equivalence relative to the initial submission, and include sample size determination, analysis methods, and acceptance criteria. To ensure that validation test datasets are representative of the intended use population, each must meet minimum demographic requirements for age, sex, race, ethnicity, and body mass index.

No modifications described in the PCCP allow adaptive learning of algorithms in the field. Modifications to all algorithms will be verified and validated and then locked prior to release. Furthermore, all modifications have the following requirements:

- No changes to the intended use of the device or its use conditions.
- Full verification per the pre-specified modification protocols.
- No device modification beyond the predefined scope of the changes.

Users are to be subsequently informed of changes via an update notice and revision of the labeling.

Table 2. *Summary of Modifications*

Type	List of Modification	Test Method
Modification to Wide Dynamic Range Compression Module	• Update the amplification coefficients • Accommodate more frequency bands	• Software and Cybersecurity Verification Tests • Hardware Bench Verification using Hearing Instrument Test (HIT) to establish substantial equivalency of amplification accuracy and frequency response smoothness.
Modification to Feedback Cancellation	• Change the order of the filter • Change of the processing frame length • Change of the filter length • Change of the adaptive filter step size	• Software and Cybersecurity Verification Tests • Hardware Bench Verification using Hearing Instrument Test (HIT) to establish substantial equivalency of feedback cancellation effectiveness. • Hardware Bench Verification Test using Head-And-Torso Simulator (HATS) to establish substantial equivalency of speech quality and total system delay.
Modification to Beamforming Algorithm	• Change of the filter coefficient	• Software and Cybersecurity Verification Tests • Hardware Bench Verification using HIT and HATS to establish substantial equivalency of beamforming effectiveness and total system delay respectively.

Type	List of Modification	Test Method
Modification to Noise Suppression Algorithm	• Change the order of the filters • Change of the processing frame length • Change of the filter length • Change of the filter types in the filter banks • Change of the weights of sound input sources	• Software and Cybersecurity Verification Tests • Hardware Bench Verification using HIT and HATS to establish substantial equivalency of signal-to-noise enhancement and total system delay respectively.
Modification to the fitting algorithm	• Update to new version of NAL-NL fitting algorithm	• Software and Cybersecurity Verification Tests • On-human Bench Verification Test to establish the substantial equivalency of the fitting accuracy against Real Ear Measurement target.

Conclusion

The subject device and predicate device have the same intended use, similar key technological characteristics, and similar acoustic capabilities. In clinical testing, Samsung Hearing Aid Feature's self-fitting strategy using Samsung Hearing Test's audiogram is non-inferior in user's perceived benefit compared to clinician administered audiogram and fitting. By meeting the clinical validation special control for self-fitting strategy, along with bench and human factor tests, Samsung demonstrated that the subject device is safe, effective, and substantially equivalent to the predicate device (DEN230081).