July 20, 2026

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

Re: K261011
Trade/Device Name: Sleep Apnea Feature (v2.0)
Regulation Number: 21 CFR 868.2378
Regulation Name: Over-The-Counter Device To Assess Risk Of Sleep Apnea
Regulatory Class: Class II
Product Code: QZW
Dated: June 16, 2026
Received: June 17, 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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2026.07.20 16:10:09 -04'00'

For

James J. Lee, Ph.D.
Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K261011

Device Name
Sleep Apnea Feature v2.0

Indications for Use *(Describe)*
The Sleep Apnea Feature is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Wearable and Phone.
This feature is intended to detect signs of moderate to severe sleep apnea in the form of significant breathing disruptions in users 18 years and older, over a two-night monitoring period. It is intended for on-demand use and requires two nights of valid data within a 10-day period.
This feature is not intended for users who have previously been diagnosed with sleep apnea. Users should not use this feature to replace traditional methods of diagnosis and treatment by a qualified clinician.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Samsung Sleep Apnea Feature v2.0
510(k) Summary
K261011

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:	July 20th, 2026

Device Information

Trade/Device Name:	Sleep Apnea Feature v2.0
Classification:	• QZW - Over-the-counter device to assess risk of sleep apnea (21 CFR 868.2378)
Predicate Device:	• Sleep Apnea Feature (DEN230041)
Reference Device	• Sleep Apnea Notification Feature (SANF) (K240929)

Device Description

The Samsung Sleep Apnea Feature v2.0 is a Software as a Medical Device (SaMD) application, requiring a pair of mobile medical apps: one on a compatible Samsung Galaxy mobile device and the other on a Samsung accessory device (either a Samsung Galaxy Watch or Samsung Galaxy Ring), which are off-the-shelf computing platforms.

Following onboarding, the feature utilizes photoplethysmography (PPG) data, accelerometer data, and PPG-derived pulse oximetry data collected from the wearable device to monitor the user's sleep periods for repetitive, significant breathing disruptions that cause significant changes in relative blood oxygenation level.

The Sleep Apnea risk assessment feature provides users with a binary classification of moderate to severe sleep apnea risk based on two nights of sufficient breathing disruption data. The algorithm calculates the time-weighted average of breathing disruption value from the two nights. If the weighted average is 15 or more breathing disruptions per hour, the user will receive a positive risk assessment along with the average breathing disruptions observed during those two nights. The user is then advised to contact their doctor to discuss this result. Additionally, the mobile application provides the user with instructions for use,

education and troubleshooting information, and the option to export their risk assessment result with breathing disruption data.

Intended Use/Indications for Use

The Sleep Apnea Feature v2.0 is indicated as follows:

> *The Sleep Apnea Feature is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Wearable and Phone.*
>
> *This feature is intended to detect signs of moderate to severe sleep apnea in the form of significant breathing disruptions in users 18 years and older, over a two-night monitoring period. It is intended for on-demand use and requires two nights of valid data within a 10-day period.*
>
> *This feature is not intended for users who have previously been diagnosed with sleep apnea. Users should not use this feature to replace traditional methods of diagnosis and treatment by a qualified clinician.*

Comparison of Technological Characteristics

The subject Sleep Apnea Feature v2.0 device is substantially equivalent to the predicate (DEN23004), as they share similar intended use, technological characteristics, and principles of operation. The difference in indications does not represent a new intended use. Both the subject and predicate devices are software-only mobile medical applications intended to detect signs of moderate-to-severe sleep apnea and are not intended to provide a standalone diagnosis.

A more detailed comparison between the subject device, the predicate device (Samsung Sleep Apnea Feature, DEN23004), and the reference device (Sleep Apnea Notification Feature, K240929) is provided in ***Table 1***.

Table 1. Technological Comparison of Subject Device, Predicate Device, and Reference Device

Characteristic	Subject Device: Samsung Sleep Apnea Feature v2.0	Predicate Device: Samsung Sleep Apnea Feature DEN230041	Reference Device: Sleep Apnea Notification Feature K240929	Comparison
Indications for Use	The Sleep Apnea Feature is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Wearable and Phone. This feature is intended to detect signs of moderate to severe sleep apnea in the form of significant breathing disruptions in users 18 years and older, over a two-night monitoring period. It is intended for on-demand use and requires two nights of valid data within a 10-day period. This feature is not intended for users who have previously been diagnosed with sleep apnea. Users should not use this feature to replace traditional methods of diagnosis and treatment by a qualified clinician.	The Sleep Apnea Feature is an over- the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone. This feature is intended to detect signs of moderate to severe obstructive sleep apnea in the form of significant breathing disruptions in adult users 22 years and older, over a two- night monitoring period. It is intended for on demand use. This feature is not intended for users who have previously been diagnosed with sleep apnea. Users should not use this feature to replace traditional methods of diagnosis and treatment by a qualified clinician. The data provided by this device is also not intended to assist clinicians in diagnosing sleep disorders.	The Sleep Apnea Notification Feature (SANF) is a software-only mobile medical application that analyzes Apple Watch sensor data to identify patterns of breathing disturbances suggestive of moderate-to-severe sleep apnea and provides a notification to the user. This feature is intended for over-the-counter (OTC) use by adults age 18 and over who have not previously received a sleep apnea diagnosis and is not intended to diagnose, treat, or aid in the management of sleep apnea. The absence of a notification is not intended to indicate the absence of sleep apnea.	The indications for use of the subject device deviate from the predicate due to the expanded user population (adult users over 18 rather than 22), which is the same as the reference device and supported by clinical validation study.
Principle of Operation	The Sleep Apnea Feature uses software algorithms to analyze input PPG, accelerometer, and blood oxygen signals and provide a risk assessment for sleep apnea.	The Sleep Apnea Feature uses software algorithms to analyze input blood oxygen sensor signals and provide a risk assessment for sleep apnea.	SANF uses software algorithms to analyze input accelerometer sensor signals and provide a risk assessment for sleep apnea.	Substantially equivalent to predicate device
Overall Device Design	A software-only device, and uses software algorithms to analyze input sensor signals from a general-purpose computing platform and provide a risk assessment for sleep apnea.	A software-only device, and uses software algorithms to analyze input sensor signals from a general-purpose computing platform and provide a risk assessment for sleep apnea.	A software-only device, and uses software algorithms to analyze input sensor signals from a general-purpose computing platform and provide a risk assessment for sleep apnea.	Substantially equivalent to predicate device

Characteristic	Subject Device: Samsung Sleep Apnea Feature v2.0	Predicate Device: Samsung Sleep Apnea Feature DEN230041	Reference Device: Sleep Apnea Notification Feature K240929	Comparison
	Assessments are based on sensor data collected over a 2-day period. The device is intended to provide a risk assessment for signs of moderate to severe sleep apnea.	Assessments are based on sensor data collected over a 2-day period. The device is intended to provide on demand assessments to detect signs of sleep apnea, such that a user must actively choose to initiate a monitoring period.	Assessments are based on sensor data collected over 30-day periods. The device is intended to provide opportunistic detection of sleep apnea, such that after initial enrollment no user interaction is required for the device to perform as intended.	
OTC/Rx	Over-the-counter	Over-the-counter	Over-the-counter	Same as predicate device.
Use Environment	Home	Home	Home	Same as predicate device.
Device Components	Software-only	Software-only	Software-only	Same as predicate device.
Device Input	Blood oxygen level (SpO_2) data, PPG data, Accelerometer Data, Sleep Data.	Blood oxygen level (SpO_2) data, Sleep Data	Accelerometer data	Substantially equivalent to the predicate device
Key Sensor	PPG, Accelerometer	PPG, Accelerometer	Accelerometer	Uses the key sensor from both the predicate and reference device
Clinical Performance	Watch: Sensitivity: 90.8% 95% CI [86.0%, 94.4%] Specificity: 90.3% 95% CI [86.1%, 93.6%] Ring: Sensitivity: 77.9% 95% CI [71.5%, 83.5%] Specificity: 95.9% 95% CI [92.8%, 97.9%]	Sensitivity: 82.7% 95% CI [76.7%, 87.6%] Specificity: 87.7% 95% CI [83.1%, 91.4%]	Sensitivity: 66.3% 95% CI [62.2%, 70.3%] Specificity: 98.5% 95% CI [98.0%, 99.0%]	Clinical performance of the subject device operating on Watch is improved compared to the predicate device. Subject device operating on Ring is substantially equivalent to the reference device.
Algorithms	PPG and accelerometer-based algorithm to detect desaturation events	PPG-based algorithm to detect desaturation events	Accelerometer-based algorithm to detect breathing changes	Substantially equivalent to the predicate and reference device

Characteristic	Subject Device: Samsung Sleep Apnea Feature v2.0	Predicate Device: Samsung Sleep Apnea Feature DEN230041	Reference Device: Sleep Apnea Notification Feature K240929	Comparison
Platforms	Galaxy Watch6 running WearOS 5.0, Galaxy Ring running latest firmware, Galaxy mobile phone with Android 12	Galaxy Watch4 or later running WearOS 5.0+, Galaxy mobile phone with Android 9+	Apple Watch Series 9 or later, Apple Watch Ultra 2, iPhone with iOS 18+	Substantially equivalent to predicate device, Galaxy Ring provides the same type of sensors as Galaxy Watch.

Performance Data

Algorithm Development

Samsung Sleep Apnea Feature v2.0 includes a revised deep learning algorithm that identifies breathing disruptions and classify sleep apnea using photoplethysmography and accelerometer data from Galaxy Watch or Galaxy Ring. The model was trained on wearable sensor data collected during approximately 2400 concurrent in-lab polysomnography (PSG) recordings from more than 1100 subjects with varying clinical categories for sleep apnea. The development dataset included a diverse group of subjects in terms of age, gender, ethnicity, and BMI that appropriately represented the intended users of the device. The development dataset was divided into training, validation, and test sets. This standard algorithm development method ensures no subject overlap and matches distributions of demographics. After algorithm development was complete, the model was locked prior to verification and validation.

Non-clinical Testing

The following tests were conducted, showing that the subject SaMD demonstrates safety, effectiveness, and substantial equivalence to the predicate and reference devices. No new safety issues were found during this testing.

- Software Verification Testing following recommendations in FDA's 2023 Guidance, "Content of Premarket Submissions for Device Software Functions", at Basic Documentation Level.
- Cybersecurity testing that adheres to FDA's 2023 Guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."
- Labeling Verification Testing

Off-the-Shelf Commercial Platform (Hardware and Software) Assessment

Per FDA's 2020 Guidance, "Multiple Function Device Products: Policy and Considerations", testing was performed on different aspects of the commercial platform hosting the subject SaMD (i.e., representing other functions), showing they do not negatively impact safely and effectiveness of the subject SaMD. This included the following:

- SpO_2 Bench Testing
- Low Perfusion Bench Testing
- Platform Interface Software Testing (Android and WearOS)
- Platform Interface Hardware Testing
    - General safety tests: Electrical safety, electromagnetic compatibility, radio frequency emissions, material safety for skin contact, thermal safety for skin contact tests

- Device robustness tests: Resistance to electrostatic discharge, water ingress and breakage tests.

Human Factor Validation:

To evaluate the effectiveness of control measures designed to reduce or eliminate use-related hazards and/or potential use errors, especially those associated with moderate harm including over-relying on the Samsung Sleep Apnea Feature 2.0 in a way that leads to delayed or no medical treatment of a serious condition, a human factor validation study was conducted in accordance with the following guidance documents:

- Food and Drug Administration. (2016). Applying human factors and usability engineering to medical devices: guidance for industry and Food and Drug Administration staff
- IEC 62366-1, Medical devices – Application of usability engineering to medical devices, which is published by the International Electrotechnical Commission and has been adopted in the United States as ANSI/AAMI/IEC 62366-1:2015+AMD1:2020
- IEC TR 62366-2, Medical devices—Part 2: Guidance on the application of usability engineering to medical devices, which is published by the International Electrotechnical Commission (adopted in the United States as AAMI/IEC TIR62366-2:2016)

Clinical Testing

The Sleep Apnea Feature was validated via a prospective, multi-center study where study participants (i.e., an enriched population of individuals aged 18 and older) underwent a 2-night polysomnography (PSG) study while simultaneously wearing a Samsung Galaxy Watch (n = 475) and Samsung Galaxy Ring (n = 469) with the Sleep Apnea Feature. The completed study included subjects across the spectrum of sleep apnea severity classifications (Normal, Mild, Moderate, and Severe), ensuring appropriate representation for each apnea-hypopnea index (AHI) range.

The Sleep Apnea feature's sensitivity and specificity was assessed when identifying subjects who exhibited moderate-to-severe sleep apnea during that 2-night PSG study for both watch and ring platforms (***Table 2***).

Table 2*. Classification Performance Analysis*

Watch (N=475)		**Ring** (N=469)	
Sensitivity	**Specificity**	**Sensitivity**	**Specificity**
90.8% 95% CI [86.0%, 94.4%] (188 of 207)	90.3% 95% CI [86.1%, 93.6%] (242 of 268)	77.9% 95% CI [71.5%, 83.5%] (155 of 199)	95.9% 95% CI [92.8%, 97.9%] (259 of 270)

Furthermore, additional analysis demonstrated:

1. The Sleep Apnea Feature was able to provide classification for 87.9% of sleep sessions for the watch and 86.0% of sleep sessions for the ring.
2. The Sleep Apnea Feature provided breathing disruption measurements within the pre-specified breathing disruption accuracy zones[1] in 90.0% of the subjects for the watch and 89.8% of the subjects for the ring.

Observed performance for relevant subgroups is shown in ***Table 3*** showing the Sleep Apnea Feature's classification performance is reasonably consistent across the subgroups.

Table 3. *Subgroup Performance Analysis*

			Watch			Ring	
		N	Sensitivity	Specificity	N	Sensitivity	Specificity
Gender	Male	229	94.1%	88.3%	231	85.5%	92.0%
	Female	246	84.7%	91.4%	238	63.2%	98.2%
Age	<40	128	86.5%	95.6%	126	66.7%	98.9%
	40-55	165	94.6%	91.2%	164	81.7%	92.5%
	55+	182	89.6%	83.7%	179	78.9%	96.4%
BMI (lb/in^2)	<25	53	83.3%	91.5%	53	85.7%	97.8%
	>= 25	422	91.0%	90.0%	416	77.6%	95.5%
Skin Tone (Monk Scale)	1-4	147	97.0%	90.0%	147	80.9%	100%
	5-6	159	84.4%	93.7%	158	71.0%	100%
	7-10	169	90.8%	87.1%	164	81.2%	88.4%

Predetermined Change Control Plan (PCCP)

The Samsung Sleep Apnea Feature v2.0 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 and validation activities that will support the proposed potential changes (see ***Table 4***). The modification protocols incorporate impact assessment considerations and specify requirements for data management, including data sources, collection, storage, and sequestration, as well as documentation and data re-use practices. Specific test methods are detailed to establish substantial equivalence relative to the initial submission and include analysis methods and acceptance criteria. To ensure that the validation test dataset is representative of the intended use population, it specifies demographic requirements for age, sex, race, ethnicity, sleep apnea severity, and body mass index.

[1] Breathing disruption accuracy zones are set at ± 5 at 0 PSG apnea-hypopnea index (AHI), ± 10 at 15 AHI, ± 15 at 30 AHI.

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

- No concurrent changes to hardware sensors or sensor framework functions on the wearable platform
- No changes to the intended use of the device or its use conditions.
- Full verification and validation through pre-specified modification protocols.

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

Table 4. *Summary of Modifications*

Type	List of Modification	Test Method
Modifications to the respiratory event detection and breathing disruption computation	• Modifications to the SpO_2 signal quality check module	Comparative analysis to establish substantial equivalency of SpO_2 performance to the original clearance
	• Modifications to the pre-processing and segmentation of model input data • Modification to the breathing disruptions algorithm's hyper-parameters • Re-training of the breathing disruptions calculation neural network • Modification to the breathing disruptions regression fitting	Comparative analysis to establish substantial equivalency of classification (sensitivity and specificity) and breathing disruption performance to the original clearance
Modifications to sleep apnea classification logic	• Modification to sleep session data requirement and merging logic • Modifications of data requirement for calculating classification result • Modifications to multi-night sleep apnea classification logic	Comparative analysis to establish substantial equivalency of classification (sensitivity and specificity) performance to the original clearance

Conclusion

The subject device and predicate device have the same intended use, the same key technological characteristics, and similar signal-acquisition capabilities. In clinical testing, Samsung's updated Sleep Apnea Feature v2.0 demonstrated that it has comparable sleep apnea classification performance as the predicate (DEN230041). Combined with passing bench and human factors tests, we conclude that the subject device is safe, effective, and possesses an appropriate level of specificity and sensitivity for general population obstructive sleep apnea risk assessment. Therefore, Samsung Sleep Apnea Feature v2.0 is substantially equivalent to the Samsung Sleep Apnea Feature (DEN230041).