September 13, 2024

Apple Inc.
Lynda Ikejimba
Principal Regulatory Affairs Associate
One Apple Park Way
Cupertino, California 95014

Re: K240929
Trade/Device Name: Sleep Apnea Notification Feature (SANF)
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: April 4, 2024
Received: April 4, 2024

Dear Lynda Ikejimba:

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) titled “SLEEP APNEA NOTIFICATION FEATURE (SANF) PREDETERMINED CHANGE

CONTROL PLAN" version 1.0. 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240929

Device Name

Sleep Apnea Notification Feature (SANF)

Indications for Use *(Describe)*

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.

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

Prescription Use (Part 21 CFR 801 Subpart D)

X 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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

1. Submitter

Applicant	Apple Inc. One Apple Park Way Cupertino, CA 95014
Submission Correspondent	Lynda Ikejimba, PhD Regulatory Affairs Phone: (669) 227-8858 Email: lc_ikejimba@apple.com
Secondary Correspondent	Kevin Go Regulatory Affairs Phone: (669) 225-1032 Email: kevin_f_go@apple.com
Date Prepared	Sept 13, 2024

2. Device Names and Classifications

Subject Device:

Name of Device	Sleep Apnea Notification Feature (SANF)
Classification Name	Over-the-counter device to assess risk of sleep apnea, 21 CFR 868.2378
Regulatory Class	Class II
Product Code	QZW
510(k) Review Panel	Anesthesiology

3. Predicate Device

Predicate Manufacturer	Samsung Electronics Co., Ltd
Predicate Trade Name	Sleep Apnea Feature
Predicate 510(k)	DEN230041

4. Device Description

The Sleep Apnea Notification Feature (SANF) is an over-the-counter mobile medical application (MMA) intended to identify patterns of breathing disturbances suggestive of moderate-to-severe sleep apnea and provide a notification to the user. SANF is intended to run on compatible iOS (e.g. iPhone, iPad) and Apple Watch platforms. Users set up SANF and view their health data on the iOS platform. Prior to use, users must undergo educational onboarding. SANF uses accelerometer sensor data collected by the Apple Watch to calculate breathing disturbance values while a user is asleep. Breathing disturbances describe transient changes in breathing patterns, such as temporary breathing interruptions.

Breathing disturbance data is analyzed in discrete, consecutive 30-day evaluation windows. If patterns consistent with moderate-to-severe sleep apnea are identified within the 30-day evaluation window, the user is notified. SANF provides visualizations depicting the user's breathing disturbance data over various time scales. SANF is not intended to provide instantaneous measurements. Instead, once activated, SANF runs opportunistically in the background receiving signals from Apple Watch sensors for processing.

5. Indications for Use

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.

6. Comparison with the Predicate Device

SANF and the predicate device (DEN230041) have the same intended use, technological characteristics, and principles of operation, and 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 for individuals who have not been previously diagnosed with sleep apnea and are not intended to provide a standalone diagnosis.

The subject device contains some differences in technological characteristics:

- The subject device is compatible with Apple products (i.e., iOS device, Apple Watch), while the predicate is compatible with Samsung products (i.e., Galaxy Watch and Phone).
- The subject device utilizes passive, opportunistic detection to monitor the user over a 30-day period, and only alerts the user if it detects signs of sleep apnea. The predicate device provides an on-demand two-day assessment, and returns either a positive or negative finding to the user.
- The subject device utilizes accelerometer sensor data while the predicate device utilizes blood oxygen sensor data.

The differences in technological characteristics described above do not raise new questions of safety or effectiveness. The differences can properly be evaluated through the special controls

established in 21 CFR 868.2378. The subject device has been appropriately verified and validated through non-clinical and clinical testing to ensure that the device is substantially equivalent to the predicate. A complete comparison of the subject and predicate device can be found in Table 1 below.

Table 1: SANF Comparison with the Predicate

Item	Subject Device Sleep Apnea Notification Feature	Predicate Device (DEN230041)
Device Name	Sleep Apnea Notification Feature (SANF)	Sleep Apnea Feature
Manufacturer	Apple Inc.	Samsung Electronics Co., Ltd
Regulation Number	21 CFR 868.2378	21 CFR 868.2378
Product Code	QZW	QZW
Regulation Name	Over-the-counter device to assess risk of sleep apnea	Over-the-counter device to assess risk of sleep apnea.
Device Classification	Class II	Class II
OTC/Prescription	OTC	OTC
Intended Use	An over-the-counter device to assess risk of sleep apnea intended to provide a notification of the risk of sleep apnea in users who have not been previously diagnosed with sleep apnea. This device uses software algorithms to analyze input sensor signals and provide a risk assessment for sleep apnea. It is not intended to provide a standalone diagnosis, replace traditional methods of diagnosis (e.g., polysomnography), assist clinicians in diagnosing sleep disorders, or be used as an apnea monitor.	An over-the-counter device to assess risk of sleep apnea is intended to provide a notification of the risk of sleep apnea in users who have not been previously diagnosed with sleep apnea. This device uses software algorithms to analyze input sensor signals and provide a risk assessment for sleep apnea. It is not intended to provide a standalone diagnosis, replace traditional methods of diagnosis (e.g., polysomnography), assist clinicians in diagnosing sleep disorders, or be used as an apnea monitor.

Item	Subject Device Sleep Apnea Notification Feature	Predicate Device (DEN230041)
Indications for Use	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 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.
Principle of Operation	SANF uses software algorithms to analyze input accelerometer sensor 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.
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. 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.	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. 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.
Use Environment	Over-the-counter	Over-the-counter
Device Components	Software-only	Software-only
Device Input	Accelerometer data	Blood oxygen level (SpO_2) data

Item	Subject Device Sleep Apnea Notification Feature	Predicate Device (DEN230041)
Clinical Performance	The performance was optimized for high specificity given SANF is designed as an opportunistic detection feature (i.e., passive, recurring). Sensitivity: 66.3% 95% CI [62.2%, 70.3%] Specificity: 98.5% 95% CI [98.0%, 99.0%]	 Sensitivity: 82.7% 95% CI [76.7%, 87.6%] Specificity: 87.7% 95% CI [83.1%, 91.4%]

7. Summary of Non-Clinical Testing

Algorithm Development

SANF includes a deep learning algorithm to identify breathing disturbances using accelerometer sensor data from Apple Watch. The model was trained on Apple Watch accelerometer signals collected during sleep sessions with concurrent in-lab polysomnography (PSG) and Home Sleep Apnea Test (HSAT) reference recordings. The algorithm development dataset included over 11,000 nights of concurrent reference and watch sensor data. The distribution of sleep apnea classifications in this dataset was broad and spanned all four clinically defined categories of sleep apnea: normal (AHI 0 to <5), mild (AHI 5 to <15), moderate (AHI 15 to <30), and severe (AHI ≥30). For the purposes of algorithm development, data from the studies was pooled and split into four sets: Training, Validation, Test, and Sequestration. The model was trained on the Training set, with the Validation set used for early stopping and threshold selection. The model was then evaluated on the Test set at regular intervals during model development. When development was complete and the model was locked, it was evaluated on the Sequestration set as a last test to ensure it had not been over-fit to the training data. This process ensured no subject overlap and matching distributions of sex, age, BMI, and disease severity. The development data included a diverse group of subjects with respect to demographic factors (e.g., age, AHI, race, ethnicity, and BMI) representative of the intended use population.

Non-clinical Testing Summary

Apple conducted the necessary non-clinical testing on SANF with passing results supporting a determination of substantial equivalence. Non-clinical testing conducted included the following:

Software Verification and Validation
Software verification and validation was conducted in accordance with Apple's robust Quality Management System and documented to address the recommendations in FDA's 2023 Guidance, "Content of Premarket Submissions for Device Software Functions." SANF was determined to require a Basic Documentation Level. Apple's good software engineering practices, as demonstrated through the submission's documentation, supports a conclusion that SANF was appropriately designed, verified, and validated.

Cybersecurity

Apple approach to cybersecurity aligns with FDA's 2023 Guidance, " Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions." The device also conforms to the cybersecurity requirements identified in Section 524B to the FD&C Act.

Human Factors Validation

The Sleep Apnea Notification Feature was found to be safe and effective as compared to the predicate for the intended users, uses, and use environments. This conclusion is supported by iterative human factors analyses and evaluations on the device, resulting design modifications and the analysis of the summative validation testing results as recommended by 2016 FDA Guidance , "Applying Human Factors and Usability Engineering to Medical Devices".

General Purpose Computing Platform Assessment

SANF is a software-only device available on compatible general purpose computing platforms (e.g. Apple Watch); therefore, medical device hardware testing is not applicable. However, as a multiple function device product, the impact of the general purpose computing platform on SANF was assessed per FDA's 2020 Guidance, "Multiple Function Device Products: Policy and Considerations" and determined to be acceptable. This is consistent with the impact assessment of other Apple medical device features made available on Apple Watch, such as the Irregular Rhythm Notification Feature (K231173) and the Atrial Fibrillation History Feature (K213971).

8. Summary of Clinical Testing

The performance of the Sleep Apnea Notification Feature was validated in a prospective, non-significant risk study enrolling 1,499 subjects from several sites across the United States. The purpose of the study was to evaluate the performance of SANF using the Nox T3s home sleep apnea testing (HSAT) device (K192469) as a reference device. The study enrolled subjects across the spectrum of sleep apnea severity classifications, with a broad distribution across each of the following AHI categories using the "4%" hypopnea scoring rule: 559 normal subjects (AHI < 5), 362 mild subjects (5 ≤ AHI < 15), 216 moderate subjects (15 ≤ AHI < 30), and 201 severe subjects (AHI ≥ 30), plus 161 subjects with missing HSAT reference. Subjects were also enrolled based across a broad range of demographic factors, including enrollment targets for age, sex, BMI, skin tone, race, and ethnicity subgroups to ensure the study population was representative of the intended user population. Study demographic characteristics are summarized in Table 2 below.

Table 2: SANF Clinical Study Subject Demographics

N = 1,499	
Age Group (years)	
18-49	855 (57.0%)
50-64	491 (32.8%)
≥65	153 (10.2%)
Sex	

Female	847 (56.5%)
Male	652 (43.5%)
Ethnicity	
Hispanic or Latino	181 (12.1%)
Non-Hispanic or Latino	1,318 (87.9%)

Race	
American Indian or Alaska Native	25 (1.7%)
Asian	103 (6.9%)
Black or African American	347 (23.1%)
Native Hawaiian or Other Pacific Islander	3 (0.2%)
White	1,021 (68.1%)

Of the 1,499 enrolled subjects, 1,278 contributed to the notification performance analysis and 1,305 contributed to the breathing disturbance performance analysis. Those not included in the performance had insufficient Apple Watch data and/or reference data.

The sensitivity of notifications for subjects with moderate-to-severe sleep apnea (AHI ≥ 15) was 66.3%; 95% CI [62.2%, 70.3%]. The specificity of the notifications for those with normal-to-mild sleep apnea (AHI
< 15) was 98.5%; 95% CI [98.0%, 99.0%]. SANF did not falsely notify any subjects with normal AHI (AHI < 5). The performance was similar for identified sub-groups.

To assess performance of Breathing Disturbance estimates, Apple evaluated the proportion of paired (Breathing Disturbance, reference AHI). Of the total 1,305 subjects who had at least one paired measurement, 1,193 (91.4%) were within the pre-specified performance zone.

These results demonstrate that the Sleep Apnea Notification is effective in generating accurate notifications for moderate-to-severe sleep apnea and Breathing Disturbance values.

9. Predetermined Change Control Plan

The SANF 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 does not include provisions for implementation of adaptive algorithms that will continuously learn in the field. All algorithm modifications will be trained, tuned, and locked prior to release of the software to the field. A procedure has also been established for updating the Instructions for Use in order to inform users about algorithm changes implemented under this FDA-authorized PCCP, including a summary of the changes, a characterization of algorithm performance, and the availability and compatibility of the feature. Apple will publish updated Instructions for Use on its website and make them accessible within the Health App.

The PCCP specifies possible modifications to the device software as well as verification and validation activities in place to implement the changes in a controlled manner such that the modified device remains as safe and effective as the predicate device. The PCCP includes a specific list of potential software modifications defining the region of potential changes that can be made to the algorithms in the device. Details of the potential changes are summarized in **Table**

3 below. 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 Sleep Apnea Notification Feature and include sample size determination, analysis methods, and acceptance criteria. To help ensure validation test datasets are representative of the intended use population, each will meet minimum demographic requirements for age, sex, race, BMI and ethnicity.

Table 3: Proposed modifications to the SANF under the PCCP

	Detailed List of Changes	Requirements	Test Method
Modifications to Breathing Disturbances (BD) computation	• Adjust the operating point • Re-train algorithm with additional datasets while maintaining the same algorithm architecture and number of parameters. • Revise signal input module • Add additional classifier outputs • Modifications to signal quality and post-processing modules	• No change to input type • No change to output type • No concurrent change to other modules • No change to intended use of device • Can be fully verified and/or validated by requirements of the modification protocol	Verification of BD accuracy and substantial equivalence in notification-level sensitivity and specificity when compared to the performance of SANF 1.0
Modifications to sleep apnea estimation	• Modify the number of nightly BD readings required to surface a notification • Reduce the interval of the notification window • Modify logic for surfacing a notification based on BDs		Substantial equivalence in sensitivity and specificity when compared to the performance of SANF 1.0

10. Conclusion

The Sleep Apnea Notification Feature is substantially equivalent to the predicate device as they are identical with respect to intended use and there are no differences in technological or performance characteristics that raise different questions of safety and effectiveness.