Samsung Electronics Co., Ltd
% Matthew Wiggins, Ph.D.
MPS-HSL Lab Head
Samsung Research America
665 Clyde Avenue
Mountain View, CA 94043

Re: DEN230041
Trade/Device Name: Sleep Apnea Feature
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: May 31, 2023
Received: May 31, 2023

Dear Dr. Wiggins:

This letter corrects our previous classification order, dated February 6, 2024, to correct the regulation number.

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 Sleep Apnea Feature, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Sleep Apnea Feature, and substantially equivalent devices of this generic type, into Class II under the generic name over-the-counter device to assess risk of sleep apnea.

FDA identifies this generic type of device as:

> **Over-the-counter device to assess risk of sleep apnea.** 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.

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 May 31, 2023, FDA received your De Novo requesting classification of the Sleep Apnea Feature. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Sleep Apnea Feature 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 Sleep Apnea Feature 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**
False negative resulting in failure to assess risk of sleep apnea and delay of further evaluation or treatment	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
False positive resulting in additional unnecessary medical procedures	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Misinterpretation and/or overreliance on device output, leading to: • Failure to seek treatment despite sleep apnea	Human factors testing Labeling

Risks to Health	Mitigation Measures
symptoms • Discontinuing or modifying treatment for sleep apnea	
Poor quality sensor data input to the device software function resulting in incorrect sleep apnea assessment	Non-clinical performance testing Software verification, validation, and hazard analysis Human factors testing Labeling
Electrical shock, burn, or interference with other devices (for device hardware components)	Electrical safety testing Electromagnetic compatibility (EMC) testing Labeling
Adverse tissue reaction (for device hardware components)	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the over-the-counter device to assess risk of sleep apnea is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. This testing must fulfill the following:
   (i) Testing must include a study population representative of the intended use population for the device, including subjects symptomatic and asymptomatic of sleep apnea. Any selection criteria or sample limitations must be fully described and justified.
   (ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.
   (iii) The assessment must evaluate device performance across all applicable subgroups (e.g., age, gender, body mass index (BMI), skin-tone, etc.).
   (iv) The assessment must compare device performance with a clinical comparator device (e.g., polysomnography) to demonstrate the required accuracy and/or sensitivity and specificity of the output measure(s). Justification for the clinical comparator as ground truth must be provided.
   (v) For devices with machine learning-based algorithms, the clinical validation must be completed using a dataset that is separate from the training dataset.

(2) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must demonstrate hardware compatibility and the ability of the device software and hardware to provide adequate input signal quality and handle noisy or missing data and poor signal quality.

(3) Performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical, mechanical, and thermal safety of any device hardware components.

(4) Any device hardware components that are skin-contacting must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed. Software documentation must include:

(i) Full characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.
(ii) A description of the expected impact of all applicable sensor acquisition hardware characteristics, associated hardware specifications, and processing software; and
(iii) A description of all mitigations for failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy.

(6) Human factors and usability testing must demonstrate the following:
(i) The user can correctly use the device based solely on reading the directions for use; and
(ii) The user can correctly interpret the device output and understand when to seek medical care.

(7) Labeling must include:
(i) A description of what the device measures and outputs to the user;
(ii) Hardware platform and operating system requirements;
(iii) The type of sensor data used, including specifications of compatible hardware used for data acquisition;
(iv) Warnings identifying sensor acquisition factors or subject conditions or characteristics that may impact measurement results;
(v) Information for interpretation of the measurements, including a statement that the device is not intended to replace traditional methods of diagnosis (e.g., polysomnography) nor intended to be used as an apnea monitor;
(vi) A summary of the clinical performance testing with the device, including both the device's overall performance as well as performance across all relevant subgroups.

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.

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 over-the-counter device to assess risk of sleep apnea 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 Prakhyat Singh at 301-796-6562.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health