DE NOVO CLASSIFICATION REQUEST FOR SLEEP APNEA FEATURE

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 868.2378

CLASSIFICATION: Class II

PRODUCT CODE: QZW

BACKGROUND

DEVICE NAME: Sleep Apnea Feature

SUBMISSION NUMBER: DEN230041

DATE DE NOVO RECEIVED: May 31, 2023

SPONSOR INFORMATION:

Samsung Electronics Co., Ltd
Samsung Research America
665 Clyde Avenue,
Mountain View, CA 94043 USA

INDICATIONS FOR USE

The Sleep Apnea Feature 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 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.

LIMITATIONS

DON'T use this Sleep apnea feature if you've already been diagnosed with sleep apnea.

DON'T use this Sleep apnea feature if you're under 22 years old.

Your Galaxy Watch can't catch every case of obstructive sleep apnea. The watch only checks for possible moderate to severe obstructive sleep apnea and can't detect central sleep apnea.

DON'T use this Sleep apnea feature if you've been diagnosed with any of these conditions:

- Movement related conditions: Parkinson's, Tremor, Periodic Leg Movement During Sleep (PLMS)
- Cardiac conditions: Congestive Heart Failure (CHF), atrial fibrillation
- Lung conditions: Chronic Obstructive Pulmonary Disease (COPD), chronic bronchitis, emphysema, pulmonary fibrosis.

You shouldn't use this sleep apnea feature if you're pregnant or have temporary symptoms of impaired breathing from flu, allergies, asthma, or any other condition, because your results may be inaccurate.

DON'T change the dose or schedule of any medications based on results from this feature. Always talk to your doctor first.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Samsung Sleep Apnea Feature leverages wrist-worn PPG and actigraphy technology to create an over-the-counter (OTC) assessment of moderate-to-severe obstructive sleep apnea for adults. When enabled, the device utilizes the wearable platform's PPG-derived SpO2 to monitor the user's sleep for repetitive, relative decreases in their blood oxygenation indicative of significant breathing disruptions associated with sleep apnea. Each on-demand assessment period requires two successful nights of observation within 10 days. After two qualifying assessment nights, the device will display the result on the wearable, after which, the user is guided to the phone for additional information. This provides the user with health information so that they may seek out medical attention. No raw signal data, including the SpO2 signal, is provided to the user nor is it able to be shared with clinicians.
The Samsung Sleep Apnea Feature consists of two mobile medical applications, one on the wearable (e.g., Samsung Galaxy Watch) and the other on the connected mobile phone (e.g.,

Samsung Galaxy Phone), both commercial off-the-shelf general computing platforms. Communications between the two devices are accomplished by encrypted Bluetooth/BLE connection via standard protocols for data transfer. The wearable component of the Sleep Apnea Feature runs in the wearable's operating system allowing it to verify the identification/qualification of the hardware, request SpO2/accelerometer signals via private APIs, display information on the screen display, and send data and receive commands to the phone Sleep Apnea Feature on the associated phone. The phone component of the Sleep Apnea feature provides a UI for onboarding, labeling, and status as well as the ability for device updates.

Sleep Apnea Classification Algorithm

The Sleep Apnea Feature evaluates sleep sessions by leveraging the platform's capabilities to acquire PPG signals and derive SpO2 values from those signals. After performing PPG and SpO2 signal quality checks, the algorithm performs this function using 3 steps.

1. Pre-Processing: SpO2 signal interpolation, segmentation, and feature extraction.
2. Respiratory Event Classification: Identify presence of relative SpO2 drop in each 1-minute window.
3. eAHI Estimation and Classification: Enumerate relative SpO2 dips, per-night comparison to the 15 events/hour estimated Apnea/Hypopnea Index (eAHI) threshold.

To account for internight variability, the device requires two nights of sleep data indicating moderate-to-severe sleep apnea within 10 days. The possible combinations for this two-night voting, and if it results in a notification of insufficient data or a classification, are provided in Table 1.

Table 1. Determination of the Results Based on Two Nights Within 10 days.

Classification	Night 1	Night 2
Didn't detect signs of Moderate-to-Severe Obstructive Sleep Apnea	eAHI < 15	eAHI < 15 or ≥ 15 or Insufficient Data (only if previous qualifying night eAHI <15)
Detected signs of Moderate-to-Severe Obstructive Sleep apnea	eAHI ≥ 15	eAHI ≥ 15
Insufficient Data Notification	Sleep Time < 3 Hours SpO_2 coverage < 70%	

The Sleep Apnea Feature includes machine learned algorithms. During their development datasets from representative populations were utilized from over 1000 subjects, split into separate training, tuning, and testing datasets, all maintained independently from the final verification and validation activities.

Device Software Function Inputs

The wearable hardware platform contains green/red/infrared PPG and accelerometer sensors to provide data to platform software functions that in turn process the data and output 3 data streams: "Sleep On/Off", "Sleep Off Delay", and SpO2 Data. These 3 data streams serve as inputs for the device software function algorithm blocks, while also providing data to other non-medical applications, such as Samsung Health's Sleep Tracking application.

The SpO2 signal provided by the platform is qualified by utilizing multi-channel PPG signal quality and similarity calculations, while rejecting periods of noise and motion. If the segments are determined to be valid, the platform then calculates a SpO2 value for each of the four channels of qualifying signals. Finally, the four data channels are integrated into single stream of SpO2 values.

The device software function independently verifies sufficient duration and continuity of SpO2 as it comes from the platform, verifying sufficient SpO2 abundance and continuity to appropriately evaluate sleep sessions. The device outputs an Insufficient Data Notification if the provided SpO2 signal is not sufficient for classification.

Multiple Function Device Products

This product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. Specifically, the Samsung wearable and phone host numerous other functions for non-medical, general wellness and/or general consumer purposes.

Consistent with FDA's guidance titled, "*Multiple Function Device Products: Policy and Considerations*," FDA assessed the other functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review. Samsung identified and assessed the risk of the presence of the other functions that directly contributes to the device software function, as well as those that stand apart, as a part of its System Risk Analysis. The assessment concluded that the identified risks posed by the other functions are minimal and do not impact the safety or effectiveness of the device.

SUMMARY OF NONCLINICAL/BENCH STUDIES

SOFTWARE

Samsung Sleep Apnea Feature has a Moderate Level of Concern (LOC). Appropriate documentation was provided to support the validation of the software for a Moderate LOC in accordance with FDA's 2005 guidance titled, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*."

CYBERSECURITY

Samsung approach to cybersecurity aligns with FDA's 2014 guidance titled, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." The device also conforms to the cybersecurity requirements identified in Section 524B to the FD&C Act.

PERFORMANCE TESTING - BENCH

Evaluation of Input Signal Quality

The wearable platform is responsible for acquiring the signals used by the Sleep Apnea Feature. The PPG input signal quality depends on various biological and environmental factors, which can introduce variable noise components in the signal. To support the ability of the device software function to perform as intended, the following bench testing summarized in Table 2 was submitted.

Table 2. Wearable Hardware Platform Bench Verification Testing Overview

Testing Item	Approach and Purpose
SpO_2 Data Integrity	Verify that the platform provides SpO_2 data at the correct frequency
Accelerometer Sensor Performance	Verify that the platform provides accelerometer data with a minimum sensitivity and a maximum noise

Table 3 summarizes on-human testing that verify the SpO_2 and Sleep platform functions are capable of producing quality data for the device software function to utilize.

Table 3. Wearable Platform On-Human Verification Testing Overview

Testing Item	Approach and Purpose
Sleep Time	Reprocess prior clinical validation data to ensure updates to the platform sleep detection capability does not impact clinical performance. The current platform is verified during the clinical validation.
On-human Sleep SpO_2 Accuracy	On human sleep test conducted in split healthy and sleep apnea subjects to verify real world performance of the updated hardware and/or SpO_2 platform.
On-human Sleep SpO_2 Coverage	On human sleep test conducted in split healthy and sleep apnea subjects to verify real world SpO_2 signal coverage of the updated hardware and/or SpO_2 platform.
On-human Stationary SpO_2 Accuracy	Comparing Wearable SpO_2 to Arterial Line SaO_2 per ISO80601-2-61:2017 to verify SpO_2 capability's accuracy on subjects of varied skin tones
Low Perfusion	On human bench testing to verify that low perfusion does not reduce the accuracy of SpO_2 capability on subjects of varied skin tones

Samsung also provided platform interface specifications necessary to ensure the device software function would continue to perform as intended over time.

SUMMARY OF CLINICAL INFORMATION

A non-randomized, open-label, multi-center, single-blind study was conducted in an enriched adult population with an accredited sleep lab recruiting and enrolling subjects, analyzing study results, and writing the clinical study report. The study compared the result from the Samsung Sleep Apnea Feature, the Device Under Test (DUT), with physician's assessment on corresponding PSG from an FDA-cleared PSG device as the clinical gold standard. The objective was to validate that the Samsung Sleep Apnea Feature is capable of correctly differentiating and identifying general population wearable users who show signs of moderate-to-severe obstructive sleep apnea (AHI $\geq$15) and those users who do not show signs of moderate-to-severe obstructive sleep apnea (AHI <15), as measured by sensitivity and specificity, respectively.

There were no device related adverse events. Out of 620 enrolled subjects, a total of 47 subjects did not complete the investigation.

Study Results

The Samsung Sleep Apnea Features' sensitivity was 82.7% (167 out of 202 subjects) with a 95% confidence interval of [76.7%, 87.6%], which passes the predetermined acceptance criteria. The DUT's specificity was 87.7% (235 out of 268) with a 95% confidence interval of [83.1%, 91.4%], which did not pass the acceptance criteria. The Clopper-Pearson exact binomial interval was used to determine the confidence interval for sensitivity and specificity.

The single night classification percent agreement between PSG and DUT is 84.2% (791 out of 930 nights). The device data insufficiency rate is 16.7% (205 out of 1229 nights).

While the proposed device did not pass the specificity acceptance criteria, a post-hoc analysis of the false positive subjects showed that of the 33 false positive subjects, 23 subjects (69.7%) had at least one night of positive PSG for moderate-to-severe obstructive sleep apnea (AHI $\geq$ 15). Of these 23 subjects, 10 subjects also had mild sleep apnea (AHI $\geq$ 5) on their second night and did not have a previous sleep apnea diagnosis. Though false positives by definition of the study design, the positive DUT classification benefited these 10 previously undiagnosed subjects, directing them to appropriate care and potential treatment. Considering the benefit received by these 10 subjects, a modified calculation increases specificity to 91.1% (95% lower confidence bound of 86.9%) surpassing the pre-specified specificity acceptance criteria.

Subgroup Analyses

Performance variations were observed among different subpopulation during this study. While demographic subgroups were not statistically powered for conclusive comparisons of performance, the observed performance trends in these subgroups were found to be acceptable.

During the study, 399 subjects exhibited consistent PSG results across both nights of the study; 89 subjects had a normal PSG, 108 subjects had mild OSA, 91 subjects had moderate OSA, and 111 subjects had as severe PSG. The feature correctly identified all 89 normal subjects, 98 of the 108 mild subjects, 60 of the 91 moderate subjects, and 107 of the 111 severe subjects. A follow-up analysis of the False Negative subjects within the moderate group indicated that in 22 out of the 31 subjects, the reference reported < 20 AHI on one of the two nights (12 of which report < 17 AHI). Similarly, in 24 out of the 31 subjects, the device reported

that 1 out of the 2 nights was OSA positive (eAHI ≥ 15). This analysis indicates that a significant portion of these false negative subjects are on the border of mild and moderate sleep apnea, making them difficult to classify. However, the device still benefited majority of the moderate group. The device also educates the user on common OSA symptom in device labeling through UI elements, making them more aware of their sleep apnea condition, and advises them to seek medical care if they are unwell regardless of the result. These borderline users can also choose to test again in a few months, where the device is likely to produce a positive classification if their sleep apnea has worsened.

For age, the subgroups were those under 40 years old (n = 160, sensitivity of 73.7%, specificity of 92.6%), those between 40 and 55 years old (n = 150, sensitivity of 87.9%, specificity of 86.9%), and those over 55 years old (n = 160, sensitivity of 82.7%, specificity of 79%). For gender, the subgroups were male (n = 244, sensitivity of 86.1%, specificity of 83.5%) and female (n = 226, sensitivity of 76.7%, specificity of 90.9%). For BMI, the subgroups were those with BMI lower than 25 (n = 99, sensitivity of 70%, specificity of 91%) and those with BMI greater than 25 (n = 371, sensitivity of 83.3%, specificity of 86%). For skin tone, the subgroups were those with light skin tone (Fitzpatrick Scale 1 and 2, n = 116, sensitivity of 74.1%, specificity of 94.8%), those with medium skin tone (Fitzpatrick Scale 3 and 4, n = 245, sensitivity of 85.7%, specificity of 82.7%), and those with darker skin tone (Fitzpatrick Scale 5 and 6, n = 109, sensitivity of 87.5%, specificity of 90.9%).

In populations where the disease is less prevalent, such as females (76.7% sensitivity, 90.9% specificity), Fitzpatrick Skin Tone I or II (lighter skin tone, 74.1% sensitivity, 94.8% specificity), BMI under 25 (70% sensitivity, 91% specificity), and age under 40 (73.7% sensitivity, 92.6% specificity), a trade off to achieve higher specificity at the expense of lower sensitivity is desirable for overall population accuracy of the device. Since disease prevalence in these groups is lower, the absolute number of users at risk of a false negative classification is also lower relative to other subgroups. Conversely, performance in the age over 55 group showed lower specificity and higher sensitivity, which is similarly desirable for this subpopulation.

In the subpopulation where optical SpO_2 technology is known to have lower performance (i.e., darker skin pigmentation), the DUT's sleep apnea classification accuracy exceeded that of the general population (sensitivity 87.5%, specificity 90.9%).

Finally, the clinical study had 47 subjects with low baseline perfusion. In these subjects, the sensitivity and specificity of the device were 100% and 94.1%, respectively.

Combined with passing all other endpoints in this study, it can be concluded that the device possesses an appropriate level of performance for general population obstructive sleep apnea assessment.

Human Factors and Usability Study

As an OTC device, the Human Factors Summative study included two separate portions: a Self-Selection portion and a Performance Testing portion. For the Self-Selection portion, a group of twenty adult consumers from the general public were given the Samsung Sleep Apnea Feature and the device's labeling to determine if they were an intended or non-intended user of

the device. In this session, 16 correctly identified as intended users and 4 correctly identified as non-intended users.

The performance testing portion consisted of 5 simulated use scenarios to evaluate the participants behavior after receiving the result classifications. It also included a knowledge question section focused on the participants' understanding of the product's limitations, to verify that they would not over rely on information from the product.

During the summative study, one use error occurred that was associated with a critical task, where the participant said they would not contact the doctor after receiving the notification despite suffering from sleep related symptoms. In the follow-up exchange, this participant was demonstrated to be biased toward delay of treatment behavior due to prior healthcare experiences. However, the participant did respond correctly to knowledge questions indicating the correct action was to contact an HCP because of symptoms.

Overall, participants were successful in completing onboarding and enabling the device and answered knowledge questions correctly regarding safe use and limitations of the device. The result of the summative study supports the conclusion that the Samsung Sleep Apnea Feature can be used safely and effectively by the intended users, for the intended uses, and in the intended use environments.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling for the device is sufficient and satisfies the requirements of 21 CFR 801.109. The labeling consists of Instructions for Use and an onboarding sequence. The Instructions for Use include the indications for use; a description of the device, precautions; a detailed summary of the clinical data collected in support of the device; a list of adverse events; and instructions for the safe use of the device.

Please see the Limitations section above for important contraindications, warnings, and precautions presented in the device labeling.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of an over-the-counter device to assess risk of sleep apnea.

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	Clinical performance testing Non-clinical performance testing

Risks to Health	Mitigation Measures
procedures	Software verification, validation, and hazard analysis Labeling
Misinterpretation and/or overreliance on device output, leading to: • Failure to seek treatment despite sleep apnea symptoms • Discontinuing or modifying treatment for sleep apnea	Human factors testing Labeling
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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

Sleep apnea is a severely underdiagnosed disease, with as much as 90% of the population living with sleep apnea undiagnosed[1]. Studies demonstrate that the prevalence of moderate-to-severe sleep apnea can be as high as 27.5% and has been steadily increasing in the past several decades[2,3].

A user may not realize that they are experiencing obstructive sleep apnea symptoms until after they have spoken with a clinician, receive a referral to a sleep specialist, and wait 2 to 10 months for a sleep study[4]. It is estimated that only 20% of patients report their sleep-related symptoms to their primary care physician to initiate obstructive sleep apnea testing[5]. Due to high barriers to diagnosis and treatment, patients may decide that it is not worth the time and effort to pursue a diagnosis and therefore remain undiagnosed and untreated.

The Samsung Sleep Apnea Feature provides users with an accessible assessment for this underdiagnosed disease, providing evidence to encourage the user to pursue clinical attention toward necessary diagnosis and treatment. By encouraging the general population to be more cognizant of their sleep condition, the device can reduce the negative consequences of undiagnosed obstructive sleep apnea.

Both the clinical and usability risks of the device have been evaluated and use of the device itself presents no significant direct risks to the users. Like other disease assessment devices, the key clinical risks of this proposed device are false positive and false negative classifications. False positive result can lead to user inconvenience, unnecessary additional testing and a burden to the medical system. False negatives may lead the user to think that they do not need to consult a clinician when they have moderate-to-severe sleep apnea. These risks were quantified by sensitivity and specificity in the clinical study, which demonstrated the device's safety and effectiveness in identifying the two sleep apnea classes.

The Usability Engineering Report supports the conclusion that the Samsung Sleep Apnea Feature can be used safely and effectively by the intended users, for the intended uses, and in the intended use environments. The device's UI elements reinforce to the user that they should contact their physician if they have sleep-related symptoms, mitigating the risk of false negatives. The study also demonstrated that users understand the non-diagnostic nature of the device, as well as to contact a healthcare professional if the device shows signs of moderate-to-severe OSA or if they are experiencing symptoms related to OSA, regardless of the device results.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> 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 probable benefits outweigh the probable risks for the Sleep Apnea Feature. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

References

1. Finkel KJ, Searleman AC, Tymkew H, Tanaka CY, Saager L, Safer-Zadeh E, Bottros M, Selvidge JA, Jacobsohn E, Pulley D, Duntley S, Becker C, Avidan MS. Prevalence of undiagnosed obstructive sleep apnea among adult surgical patients in an academic medical center. Sleep Med. 2009 Aug;10(7):753-8. doi: 10.1016/j.sleep.2008.08.007. Epub 2009 Jan 30. PMID: 19186102.
2. Peppard, Paul E., et al. "Increased prevalence of sleep-disordered breathing in adults." American journal of epidemiology 177.9 (2013): 1006-1014.
3. Heinzer, Raphael, et al. "Prevalence of sleep-disordered breathing in the general population: the HypnoLaus study." The Lancet Respiratory Medicine 3.4 (2015): 310-318.
4. Flemons, W. Ward, et al. "Access to diagnosis and treatment of patients with suspected sleep apnea." American journal of respiratory and critical care medicine 169.6 (2004): 668-672.
5. US Preventive Services Task Force. Screening for Obstructive Sleep Apnea in Adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2022;328(19):1945–1950. doi:10.1001/jama.2022.20304

CONCLUSION

The De Novo request for the Sleep Apnea Feature is granted, and the device is classified as follows:

Product Code: QZW
Device Type: Over-the-counter device to assess risk of sleep apnea.
Regulation Number: 21 CFR 868.2378
Class: II