



April 27, 2026

Wesper Inc.  
Ciaran Lynch  
Regulatory Manager  
44-02 11th St  
Suite 610  
Long Island City, New York 11101

Re: K252628  
Trade/Device Name: Cassie  
Regulation Number: 21 CFR 868.2375  
Regulation Name: Breathing Frequency Monitor  
Regulatory Class: Class II  
Product Code: MNR  
Dated: August 17, 2025  
Received: August 20, 2025

Dear Ciaran Lynch:

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.

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](mailto: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: 2026.04.27 16:44:26  
-04'00'

For

Rachana Visaria  
Assistant 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

## Indications for Use

510(k) Number (if known)  
K252628

Device Name  
Cassie

### Indications for Use (Describe)

Cassie is a Software as a Medical Device (SaMD) that automatically analyzes, displays, and summarizes Photoplethysmogram (PPG) data, typically collected during sleep using compatible devices. Cassie is intended for use by and by order of a healthcare professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for adults. The Wesper Apnea Hypopnea Index (wAHI) and other outputs presented when oximeter data is available are intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing.

The Cassie output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## Submitter information

**Company Name:** Wesper Inc.

**Company Address:** 234 Fifth Avenue, New York, NY 10001

**Company Contact:** Ciaran Lynch, RA Manager

**Contact Phone:** (805) 490-5223

**Contact Email:** Ciaran@wesper.co

**Date Prepared:** April 26, 2026

## Device Identification

**Name of Device:** Cassie

**Classification Name:** Breathing frequency monitor

**Regulation Number:** 21 CFR 868.2375

**Product Code:** MNR

**Device Classification:** Class II

**Classification Panel:** Anesthesiology

## Predicate Device

**Device Trade Name:** SleepImage System – K182618

**Device Manufacturer:** SleepImage

**Regulation Number:** 21 CFR 868.2375

**Product Code:** MNR

**Device Classification:** Class II

## Reference Device

**Device Trade Name:** Aurora – K231355

**Device Manufacturer:** EnsoData

**Regulation Number:** 21 CFR 868.2375

**Product Code:** MNR

**Device Classification:** Class II

## Device Description

Cassie is an Assistive Artificial Intelligence system that processes physiological data from a sleeping patient to produce clinical metrics which aid sleep professionals in diagnosing and managing sleep disorders.

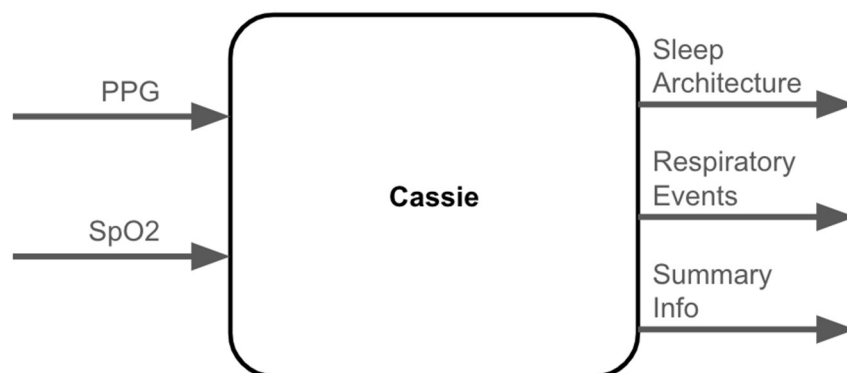
Cassie operates as a standalone software process requiring internet connectivity and AWS authorized credentials. Cassie is designed to run in a remote secure location, where it can be accessed by authorized users through an API. Cassie is designed to process Physiological data from a standard EDF file. Device outputs are generated in the form of a standard JSON file.

Data collected from a sleeping patient include:

1. Photoplethysmogram (PPG) - Optical waveform
2. SpO2 - Continuous reading of blood oxygen saturation from a peripheral site. This is an optional input.

At the output, it produces the following high-level classes of clinical metrics:

1. Sleep Architecture - an epoch-by-epoch classification of the patient's sleep stage (Wake, Light, Deep or REM)
2. Respiratory Events - instances throughout the recording time where a respiratory disturbance was registered. This output will only apply if SpO2 was provided at the input.
3. Summary Information - a distillation of the above vectorized data into physiological channels and scalar metrics, including AHI, TST, WASO, etc.



Cassie accepts the inputs, feeds them into the model, and the model's predictions set the output's labels. Cassie is currently compatible with Nonin, Inc. Model 8000 Series (K092101).

## Indications for Use

Cassie is a Software as a Medical Device (SaMD) that automatically analyzes, displays, and summarizes Photoplethysmogram (PPG) data, typically collected during sleep using compatible devices. Cassie is intended for use by and by order of a healthcare professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for adults. The Wesper Apnea Hypopnea Index (wAHI) and other outputs presented when oximeter data is available are intended to aid healthcare professionals in diagnosis and management of sleep-disordered breathing. The Cassie output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.

## Comparison to Predicate Device

### Indication for Use comparison

The subject and predicate device have the same intended use: specifically, for analyzing, summarizing and displaying data recorded from a sleeping patient.

Both the subject and predicate device rely on a PPG (Photoplethysmogram) input to calculate sleep-related parameters, such as Total Sleep Time, Sleep Efficiency and others, and have the option to also receive an SpO2 channel and produce sleep-disordered breathing information.

Similarly, both the subject and predicate device produce physiological channels and a standard output, which can be reviewed and modified by healthcare professionals using commonly available, industry-standard tools. The output from both the subject and predicate device is not intended to be interpreted or clinical action taken without the consultation of a qualified healthcare professional.

The subject device is intended for use in adults only, which is a subset of the population indicated for the predicate device (adults, adolescents, and children).

The minor differences between the predicate and subject devices do not alter the intended use of the device, nor do they raise different questions of safety and effectiveness of the subject device relative to the predicate.

### Technological Characteristics

Analysis of PPG to aid healthcare professionals in the diagnosis or management of sleep disorders is the technological foundation for both devices. In addition, the two devices share the following technological principles:

- a. Input in the form of a continuous PPG and, if available, SpO<sub>2</sub> from a sleeping patient
- b. Outputs in the form of Sleep Architecture information, such as sleep staging, total sleep time, etc., and/or Sleep-Disordered Breathing information, such as individually detected respiratory events, and wAHI (Wesper Apnea-Hypopnea Index)
- c. Cloud-based web applications, using trained machine learning models running on general-purpose computing platforms
- d. Analysis of cardiopulmonary physiological markers
- e. Graphical and numerical outputs (including physiological channels) for clinical review and verification, leveraging industry-accepted methods

Specifically, the two devices employ similar methods, techniques, technological implementations, and physiological drivers to realize all the above.

The following technological differences exist between the subject and predicate device:

### Model internals

Both devices primarily utilize cardiopulmonary information to infer physiological states related to sleep architecture and sleep-disordered breathing. While the subject device implements machine learning techniques, compared to automatic analysis of the predicate, both systems process the same underlying physiological data to achieve equivalent clinical endpoints and performance.

### Performance comparison

Key performance metrics against gold standard Polysomnography (PSG) were compared to the predicate demonstrating similar performance (See table 1 and Performance Data section for more details). For the key performance endpoints (AHI, TST & Sleep staging) correlation to PSG was similar to the predicate and similar 510(k) cleared devices. These comparisons show that any technological differences do not negatively impact safety or effectiveness.

### Summary

Based on the analysis performed above, the technological differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

### Substantial Equivalence Table

Following is a summary comparison of the two devices in tabular format:

**Table 1: Substantial Equivalence Comparison of the Subject, Predicate and Reference Device**

	<b><i>Cassie (Subject) – K252628</i></b>	<b><i>SleepImage (Predicate) – K182618</i></b>	<b><i>Aurora (Reference) – K231355</i></b>	<b><i>Similarities and Differences</i></b>
<b>Classification Regulation</b>	21 CFR 868.2375	21 CFR 868.2375	21 CFR 868.2375	Same.
<b>Product Code</b>	MNR	MNR	MNR	Same.
<b>Indications for Use</b>	<p>Cassie is a Software as a Medical Device (SaMD) that automatically analyzes, displays, and summarizes Photoplethysmogram (PPG) data, typically collected during sleep using compatible devices. Cassie is intended for use by and by order of a healthcare professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for adults. The Wesper Apnea Hypopnea Index (wAHI) and other outputs presented when oximeter data is available are intended to aid healthcare professionals in diagnosis</p>	<p>The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality. The SleepImage System analyzes, displays and summarizes Electrocardiogram (ECG) or Plethysmogram (PLETH) data, typically collected during sleep, that is intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for children, adolescents and adults. The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is</p>	<p>Aurora is a Software as a Medical Device (SaMD) that establishes sleep quality. Aurora automatically analyzes, displays, and summarizes Photoplethysmogram (PPG) data collected during sleep. Aurora is intended for use by and by order of a healthcare professional to aid in the diagnosis of sleep disorders including sleep apnea in adults. The Aurora output, including automatically detected respiratory events and parameters, may be displayed and edited by a qualified healthcare professional.</p>	<p>Similar.</p> <p>The subject device’s outputs and inputs are a subset of the predicate device’s outputs and inputs.</p>

	<p>and management of sleep disordered breathing.</p> <p>The Cassie output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.</p>	<p>intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing.</p> <p>The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.</p>	<p>The Aurora output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.</p> <p>Aurora is not intended for use with polysomnography devices.</p>	
<b>Patient Population</b>	Adults	Children, Adolescents and Adults	Adults	The subject device's patient population is a subset of the predicate's patient population.
<b>Environment of Use</b>	N/A (Software)	N/A (Software)	N/A (Software)	Same.
<b>Method of Access</b>	General-purpose computing platform with internet connection	General-purpose computing platform with internet connection	General-purpose computing platform with internet connection	Same.
<b>Principle of Operation</b>	Cloud-based web application as a Medical Device (SaMD)	Cloud-based web application as a Medical Device (SaMD)	Cloud-based web application as a Medical Device (SaMD)	Same.
<b>Input Source</b>	PPG optionally oximetry	PPG optionally oximetry	EDF signal files from compatible FDA-cleared medical purpose pulse oximeters PPG devices	Similar.

<b>Signals Analyzed</b>	PPG, optionally oximetry	ECG or PPG; optionally oximetry. Accelerometer	PPG and oximetry	Similar. The subject device's analyzed signals are a subset of the predicate device's analyzed signals.
<b>Algorithm Used</b>	Machine Learning analysis of cardiopulmonary physiological markers	Automatic analysis of cardiopulmonary physiological markers	Machine Learning analysis of cardiopulmonary physiological markers	Similar. The algorithms are substantially equivalent. While some technological differences exist, clinical performance testing and safety profiling confirm that these differences do not raise new or different questions of safety and effectiveness relative to the predicate.
<b>Interoperable Data Format</b>	EDF	EDF, ASCII	EDF	Similar.

<b>Output/Diagnostic Parameters</b>	<p>Total Sleep Time (TST)  Sleep efficiency (SE)  Sleep Latency (SL)  Wake after sleep onset (WASO)  Sleep Stages (Wake, Light, Deep REM)  Respiratory Disturbance Index (RDI)  Oxygen Desaturation Index (ODI)  Apnea/Hypopnea Index (AHI)  Obstructive Apnea/Hypopnea Index (oAHI)  Central Apnea/Hypopnea Index (cAHI)  Raw data physiological channels for review</p>	<p>Total Sleep Time (TST)  Sleep efficiency (SE)  Sleep Latency (SL)  Wake after sleep onset (WASO)  Sleep Stages (Wake, Light, Deep REM)  Respiratory Disturbance Index (RDI)  Oxygen Desaturation Index (ODI)  Apnea/Hypopnea Index (AHI)  Obstructive Apnea/Hypopnea Index (oAHI)  Central Apnea/Hypopnea Index (cAHI)  Sleep Quality index (SQI)  Sleep Fragmentation Index (SFI)  Periodicity  Raw data physiological channels for review</p>	<p>Total Sleep Time (TST)  Sleep efficiency (SE)  Sleep Latency (SL)  Wake after sleep onset (WASO)  Sleep Stages (Wake, Light, Deep REM)  Oxygen Desaturation Index (ODI)  Apnea/Hypopnea Index (AHI)  Raw data physiological channels for review</p>	<p>Similar. The subject device's output/diagnostic parameters are a subset of the predicate device's output/diagnostic parameters.</p>
<b>Performance</b>	<p>Key performance endpoints (such as AHI, TST, sleep staging etc.) were compared to the gold standard (PSG) using established clinical methodologies.</p>	<p>Key performance endpoints (such as AHI, TST, sleep staging etc.) were compared to the gold standard (PSG) using established clinical methodologies.</p>	<p>Key performance endpoints (such as AHI, TST, sleep staging etc.) were compared to the gold standard (PSG) using established clinical methodologies.</p>	<p>Similar. The subject device has a similar performance when compared to the gold standard and is in line with the predicate device and similar 510(k) cleared devices.</p>

<b>AHI [Events/hr] Performance</b> (compared to gold standard)	<u><b>Correlation to PSG</b></u> 0.96 (95% CI 0.95-0.96)  <b>Slope <math>\beta_1</math>:</b> 1.094 (1.0233, 1.1646) <b>Intercept <math>\beta_0</math>:</b> -0.2119 (-1.168, 0.7442) <b>Mean Difference (MD):</b> 1.55 (1.02, 2.08) <b>Upper Limit (ULOA):</b> 13.02 (12.12, 13.93) <b>Lower Limit (LLOA):</b> -9.92 (-10.82, -9.02)	<u><b>Correlation to PSG</b></u> $\rho = 0.89$	<u><b>Correlation to PSG</b></u> Not publicly available  <b>Slope <math>\beta_1</math>:</b> 0.936 (0.853, 1.033) <b>Intercept <math>\beta_0</math>:</b> 0.023 (-1.185, 1.122) <b>Mean Difference (MD):</b> 1.000 (0.630, 1.367) <b>Upper Limit (ULOA):</b> 14.575 (13.779, 15.363) <b>Lower Limit (LLOA):</b> -12.574 (-13.371, -11.786)	Similar. The subject device has a similar performance when compared to the gold standard and is in line with the reference device.
<b>AHI 1A cutoff &gt; 5</b>	Sensitivity: 97.3% Specificity: 86.1%	Not publicly available	Sensitivity: 92.6% Specificity: 71.6%	Similar. The subject device has a similar performance when compared to the gold standard and is in line with the reference device.
<b>AHI 1B cutoff &gt; 5</b>	Sensitivity: 97.8% Specificity: 89.9%	Not publicly available	Sensitivity: 89.4% Specificity: 76.8%	Similar. The subject device has a similar performance when compared to the gold standard and is in line with the reference device.
<b>TST [Minutes] Performance</b> (compared to gold standard)	<u><b>Correlation to PSG</b></u> $r = 0.86$  <b>Slope <math>\beta_1</math>:</b> 1.0449 (0.9964, 1.0935) <b>Intercept <math>\beta_0</math>:</b> -9.5919 (-28.3213, 9.1375)	Not publicly available	<u><b>Correlation to PSG</b></u> Not publicly available  <b>Slope <math>\beta_1</math>:</b> 1.159 (1.035, 1.318) <b>Intercept <math>\beta_0</math>:</b> -41.7 (-94.56, -0.3)	Similar. The subject device has a similar performance when compared to the gold standard and is in line with the reference device.

	<p><b>Mean Difference (MD):</b> 6.61 (2.66, 10.55)</p> <p><b>Upper Limit (ULOA):</b> 92.48 (85.73, 99.22)</p> <p><b>Lower Limit (LLOA):</b> - 79.26 (-86.01, -72.52)</p>		<p><b>Mean Difference (MD):</b> - 5.58 (-7.92, -3.54)</p> <p><b>Upper Limit (ULOA):</b> 68.7 (63.6, 72.96)</p> <p><b>Lower Limit (LLOA):</b> -79.8 (-84.84, -75.54)</p>	
<b>Data review</b>	The clinician can view raw data for interpretation, adjust epochs, and write clinical notes. Clinicians may review and utilize the results to make recommendations for further testing, referral, and/or therapy.	The clinician can view raw data for interpretation, adjust epochs, and write clinical notes. Clinicians may review and utilize the results to make recommendations for further testing, referral, and/or therapy.	The clinician can view raw data for interpretation, adjust epochs, and customize sleep reports for the patient. Clinicians may review and utilize the results to make recommendations for further testing, referral, and/or therapy.	Same.
<b>Intended Users</b>	Used by or on the order of physicians, trained technicians, or other healthcare professionals to evaluate sleep disorders where it may inform or drive clinical management taking into consideration other factors that normally are considered for clinical management of sleep disorders.	Used by or on the order of physicians, trained technicians, or other healthcare professionals to evaluate sleep disorders where it may inform or drive clinical management taking into consideration other factors that normally are considered for clinical management of sleep disorders.	Used by or on the order of physicians, trained technicians, or other healthcare professionals to evaluate sleep disorders where it may inform or drive clinical management taking into consideration other factors that normally are considered for clinical management of sleep disorders.	Same.

## Performance Data

### Software Testing:

The Cassie system is documentation level (Basic). Non-clinical testing involved validating the software requirements and ensuring proper cloud service configuration. Software development and non-clinical testing have been performed for the Cassie system in accordance with IEC 62304:2006 Medical Device Software – Software Life-Cycle Processes.

Software verification and validation testing were conducted, and documentation was provided based on Guidance Documents for Industry and FDA Staff, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions,” issued June 27, 2025, “Content of Premarket Submissions for Device Software Functions” Issued June 14, 2023, and “Software as a Medical Device (SaMD): Clinical Evaluation” (IMDRF/SaMD WG/N41FINAL:2017”).

Taken together, the non-clinical software validation and cybersecurity assessments concluded that the Cassie system performs as intended, does not introduce new questions of safety or effectiveness, and is as safe and effective for the intended use.

### Clinical Validation:

A clinical validation study was conducted to assess the accuracy of the Cassie photoplethysmography (PPG)–based home sleep testing system relative to polysomnography (PSG) and in the context of the performance characteristics of the legally marketed predicate device, the SleepImage System (K182618). The study utilized PSG recordings as the reference standard and was collected under standardized, AASM-compliant conditions with centralized scoring by certified technologists.

**Study Design:** Multi-site retrospective validation study using PSG sleep study datasets available from the National Sleep Research Resource for a similar indication for use, using PSG to assess sleep architecture, breathing patterns, and associated physiological signals.

**Study dataset:** 474 independent test subjects (25% holdout from 1,898 total studies) were taken from datasets available by the National Sleep Research Resource, supported by the

National Heart, Lung, and Blood Institute (NHLBI). The validation protocol, inclusion criteria, and statistical analysis plan were pre-specified, and analyses were conducted blinded to the reference PSG. The dataset provides PSG recordings from diverse patient populations, enabling a comparison between Wesper's PPG technology and the reference PSG device across a wide range of demographics and sleep apnea severities.

**Reference Standard:** Polysomnography (PSG) scored per AASM guidelines by certified technologists.

#### Clinical Performance:

- **Apnea-Hypopnea Index (AHI):**

Tests were performed to compare the agreement of the automated Apnea-Hypopnea Index (AHI) output from the subject device against full Polysomnography (PSG). The evaluation demonstrated a Pearson correlation of 0.96 (95% CI: 0.95-0.96) and Bland-Altman limits of agreement, -9.92 to 13.02 events/hr, relative to the reference standard.

- **Total Sleep Time (TST):**

Tests were performed to evaluate the Total Sleep Time (TST) Pearson correlation 0.86 (95% CI: 0.84-0.89) and Bland-Altman limits of agreement (LOA), -79.26 to 92.48 min, relative to the reference standard..

- **OSA Severity Classification:**

Sensitivity and specificity for detection of obstructive sleep apnea at AHI thresholds  $\geq 5$  &  $\geq 15$  events/hour under 3% and 4% desaturation criteria, using polysomnography as the reference standard. The classification accuracy of Cassie is presented in the table below:

Apnea Hypopnea Index (wAHI vs PSG)				
AHI Cutoff	Desaturation	Sample Size (n)	Sensitivity	Specificity
AHI thresholds $\geq 5$	3%	474	97.3% (95.0%, 98.5%)	86.1% (78.3%, 91.4%)
	4%	474	97.8% (95.4%, 99.0%)	89.9% (84.8%, 93.3%)
AHI thresholds $\geq 15$	3%	474	94.8% (90.9%, 97.1%)	94.7% (91.2%, 96.8%)
	4%	474	96.5% (92.0%, 98.5%)	94.9% (92.0%, 96.8%)

[Additional performance details \(secondary endpoints\):](#)

Additional endpoints listed below include Sleep Staging, Wake After Sleep Onset (WASO), Oxygen Desaturation Index (ODI), and Sleep Fragmentation Index (SFI). The performance remained consistent across age, sex, race, and BMI subgroups and none of the endpoint results exceeded predicate performance ranges or raised new questions of safety or effectiveness.

Sleep Staging			
Category	Sample Size (n)	Sensitivity	Specificity
Wake	109,763	75.2% (74.9%, 75.4%)	93.9% (93.8%, 93.9%)
Light Non-REM	244,239	66.4% (66.2%, 66.6%)	79.9% (79.7%, 80.1%)
Deep Non-REM	34,432	73.6% (73.1%, 74.0%)	86.5% (86.4%, 86.6%)
REM	63,165	73.9% (73.6%, 74.2%)	95.9% (95.8%, 95.9%)

Sleep Profile and Oxygen Saturation					
Category	Deming Regression		Bland-Altman		
	Slope $\beta 1$	Intercept $\beta 0$	Mean Difference (MD)	Upper Limit (ULO)	Lower Limit (LLO)
wAHI (3%) [events/hour]	1.094 (1.0233, 1.1646)	-0.2119 (-1.168, 0.7442)	1.55 (1.02, 2.08)	13.02 (12.12, 13.93)	-9.92 (-10.82, -9.02)
wAHI (4%) [events/hour]	1.0814 (1.0171, 1.1457)	0.4539 (-0.089, 0.997)	1.51 (1.09, 1.92)	10.55 (9.84, 11.26)	-7.54 (-8.25, -6.83)

Total Sleep Time [minutes]	1.0449 (0.9964, 1.0935)	-9.5919 (-28.321, 9.137)	6.61 (2.66, 10.55)	92.48 (85.73, 99.22)	-79.26 (-86.01, -72.52)
Sleep Fragmentation Index [events/hour]	0.7935 (0.5870, 1.0000)	2.6487 (1.389, 3.9086)	1.21 (-0.85, 1.57)	9.07 (8.45, 9.68)	-6.65 (-7.26, -6.03)
Wake After Sleep Onset [minutes]	0.9077 (0.777, 1.038)	-4.332 (-14.669, 6.003)	-13.24 (-17.39, -9.10)	76.95 (69.86, 84.03)	-103.43 (-110.52, -96.35)
Oxygen Desaturation Index [events/hours]	1.074 (0.971, 1.178)	-2.2034 (-4.568, 0.161)	-0.03 (-0.79, -0.72)	16.39 (15.10, 17.68)	-16.45 (-17.74, -15.16)

## Conclusion

Based on the results of the nonclinical and clinical testing, and the comparison to the predicate device, Cassie is substantially equivalent to the predicate device SleepImage (K182618). Cassie is as safe, as effective, and performs as well as the legally marketed predicate device for its intended use.