September 6, 2024

Withings
Khushboo Surendran
Regulatory Affairs Manager
2 Rue Maurice Hartmann
Issy-Les-Moulineaux, Ile-De-France 92130
France

Re: K231667
Trade/Device Name: Withings Sleep Rx
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: August 5, 2024
Received: August 5, 2024

Dear Khushboo Surendran:

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 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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2024.09.06 14:09:37 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231667

Device Name
Withings Sleep Rx

Indications for Use *(Describe)*

Withings Sleep Rx is indicated to record a patient's Withings index during sleep as an aid for diagnosis of obstructive sleep apnea (OSA).

The Withings Sleep Rx is also indicated to record heart rate and movement in an automatic contactless manner.

The device is designed for use in home-screening of adults with suspected possible sleep breathing disorders. Results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation. The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements, or EEG activity are required.

The device is indicated for use in adults weighing ≤ 350 lbs in a home environment during sleep and resting conditions.

This device is not indicated for active patient monitoring, as it does not provide alarms for timely response in life-threatening situations.

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.

510(k) Summary

1. Submitter

Applicant:	Withings 2 Rue Maurice Hartmann Issy-Les-Moulineaux France 92130
Submission Correspondent:	Khushboo Surendran Regulatory Affairs Manager Phone: 857-233-2681 Email: khushboo.surendran@withings.com
Back-Up Consulting Correspondent:	Michael Daniel Daniel & Daniel Consulting, LLC Email: madaniel@clinregconsult.com
Date Prepared:	September 5th, 2024

2. Subject device Information

Device Name:	Withings Sleep Rx
Regulation name:	Breathing frequency monitor
Regulation number:	21 CFR 868.2375
Regulatory Class:	Class II
Product Code:	MNR
510(k) review panel:	Anesthesiology

3. Predicates Information

Predicate Manufacturer:	Resonea, Inc
Predicate device name:	Drowzle
Predicate 510(k) number:	K173974
Reference device Manufacturer:	EarlySense Ltd.
Reference device name:	EarlySense Insight System
Reference device 510(k) number:	K152911

4. Description of the device

The Withings Sleep Rx is a device intended as an aid for diagnosis of obstructive sleep apnea (OSA). It is intended for home use. The device is placed under the mattress and is contactless with the user. It provides a Withings index based on breathing (sound, variations of pressure in the bladder) and heart rate measured in a contactless manner. The number of breathing events per hour is displayed to the user in the companion app. The results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation.

In addition, the device records heart rate and movement during sleep in an automatic contactless manner. The recordings are displayed in the companion app.

Withings Sleep Rx is composed of the following components: (1) Mat (hardware); (2) Withings Sleep Rx embedded software included in the Mat and (3) Companion App included in a companion mobile application.

5. Indications for Use

Withings Sleep Rx is indicated to record a patient's Withings index during sleep as an aid for diagnosis of obstructive sleep apnea (OSA).

The Withings Sleep Rx is also indicated to record heart rate and movement in an automatic contactless manner.

The device is designed for use in home-screening of adults with suspected possible sleep breathing disorders. Results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation. The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements, or EEG activity are required.

The device is indicated for use in adults weighing ≤ 350 lbs in a home environment during sleep and resting conditions.

This device is not indicated for active patient monitoring, as it does not provide alarms for timely response in life-threatening situations.

6. Comparison table with subject device, predicate and reference device

The following table presents a high-level comparison between the subject device (Withings Sleep Rx), the predicate device (Drowzle) and the reference device (EarlySense Bed Sensing Unit) for the indications for use, technological characteristics, and principle of operation.

Description	**Subject device Withings Sleep Rx (K231667)**	**Predicate device Drowzle (K173974)**	**Reference device EarlySense Bed Sensing Unit (K152911)**	**Comparison (Similarities/ Differences)**
Device Name	Withings Sleep Rx	Drowzle	EarlySense Insight System	N.A.
Manufacturer	Withings	Resonea, Inc	EarlySense Ltd	N/A
Regulation number	868.2375	868.2375	868.2375	Identical

Description	Subject device Withings Sleep Rx (K231667)	Predicate device Drowzle (K173974)	Reference device EarlySense Bed Sensing Unit (K152911)	Comparison (Similarities/ Differences)
Class	II	II	II	Identical
Product code	MNR	MNR	BZQ	Identical to predicate
510(k) Review panel	Anesthesiology	Anesthesiology	Anesthesiology	Identical
Prescription / OTC	Prescription	Prescription	Prescription	Identical
Intended population	Adults	Adults	Adults, adolescents, and children	Identical to predicate.
Intended environment for use	Home environment	Home environment	Home and Clinical environment	Identical to predicate.
Intended Use	Home-use device for aiding to diagnosis patients with possible sleep disorders.	Home-use device for screening patients with possible sleep disorders.	Intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner.	Identical to predicate
Indications for use	Withings Sleep Rx is indicated to record a patient's Withings index during sleep as an aid for diagnosis of obstructive sleep apnea (OSA). The Withings Sleep Rx is also indicated to record heart rate and movement in an automatic contactless manner. The device is designed for use in home-screening of adults with suspected possible sleep breathing disorders. Results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation. The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb	Drowzle is indicated to record a patient's respiratory pattern during sleep for the purpose of pre-screening patients for obstructive sleep apnea (OSA) syndrome. The device is designed for use in home-screening of adults with suspected possible sleep breathing disorders. Results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation. The system is not intended as a substitute for full polysomnography	The EarlySense Bed Sensing Unit is an accessory that is compatible with bedside units of EarlySense Systems (Models 2.0 and InSight) intended for continuous measurement of respiration rate, **heart rate and movement, in an automatic contact-less manner**. Environment of use for the accessory is defined as per compatible cleared bedside units labeling: EarlySense 2.0 - at home, in hospital or clinic setting and InSight - in hospital or clinic setting. The device is indicated for use in children, adolescents and adults.	Identical to predicate. In addition, the indication for movement detection and heart rate estimation in a contact-less manner is identical to the reference device.

Description	Subject device Withings Sleep Rx (K231667)	Predicate device Drowzle (K173974)	Reference device EarlySense Bed Sensing Unit (K152911)	Comparison (Similarities/ Differences)
	movements, or EEG activity are required. The device is indicated for use in adults weighing ≤ 350 lbs in a home environment during sleep and resting conditions. This device is not indicated for active patient monitoring, as it does not provide alarms for timely response in life-threatening situations.	when additional parameters such as sleep stages, limb movements, or EEG activity are required.	The operation of the EarlySense system has been studied in children (weight ≥10 Kg) and adults (weight <111 Kg) during sleep and resting condition.	
Device placement and patient contact	The Withings Sleep Rx is placed under the bed mattress - not touching the patient	Smartphone placed within 24 inches of pillow	The Bed Sensing Unit is placed under the bed mattress - not touching the patient	Identical. All the devices are contactless.
Sensor Technology	A pneumatic bladder with a pressure sensor is used to detect motion signals (mechanical movements) in a contact-less manner. These signals are converted into an electrical signal, sampled, filtered and transferred to the embedded microcontroller where they are analyzed by the device's software (algorithms) to provide the Withings index, heart rate (HR), and movement. Bed exit signal is also detected and available. The signal of the pneumatic sensor is also decomposed into a breathing component by the algorithm (not shown to the patient).	N/A	Piezoelectric ceramic sensing element is used to detect motion signals (mechanical movements) in a contact-less manner. These signals are converted into an electric signal, sampled, filtered and transferred to the Bedside Unit where they are analyzed by the Bedside unit's software (algorithms) to provide the respiration rate (RR), heart rate (HR), and motion. Bed exit signal is also detected and available.	Similar to the reference device. Both devices detect motion signals (mechanical movements) in a contact less-manner. Both devices estimate the same parameters: heart rate (HR), movement and bed exit detection except for respiratory rate.
	Device also includes an audio sensor	Microphone(s) native to smartphone placed	N/A	Similar to the predicate device. Both devices

Description	Subject device Withings Sleep Rx (K231667)	Predicate device Drowzle (K173974)	Reference device EarlySense Bed Sensing Unit (K152911)	Comparison (Similarities/ Differences)
	(microphone) that analyzes sound to identify breathing sound and estimates gaps in breathing sounds.	within 24 inches of pillow analyzes sound to identify breathing sound and estimates gaps in breathing sounds.		are placed close to the user in a contactless manner to record breathing sounds. The subject device combines the breathing sounds with pressure changes measured by the pressure sensor to estimate respiratory events indicative of sleep apnea whereas the predicate device uses only the breathing sounds to estimate respiratory events indicative of sleep apnea.
Material used	Inner bladder: thermoplastic polyurethane Outer Protective fabric: Polyester	N/A	ABS/Polycarbonate plate	Different. This difference does not affect safety due to the contactless nature of the device.
Signals acquired	Sounds from respiration. Pressure changes due to body motion, chest movement (respiration), and vibrations created by the heart.	Sounds from respiration.	Piezoelectric signal generated by variations of pressure applied on the device due to body motion, chest movement (respiration), and vibrations created by the heart.	Similar to predicate and reference device
Algorithm processing	Analyzes sound and pressure signals to identify respiratory events indicative of sleep apnea or other disorders. Analyzes the pressure signal to calculate heart rate and detect movements.	Analyzes the sound signal to identify respiratory events indicative of sleep apnea or other disorders	Analyzes the piezoelectric signal to calculate heart rate and respiration rate, and to detect movements.	The subject device analyzes the measured signals similarly to the predicate and reference device.
Algorithm outputs displayed to the user	Withings index (estimated frequency of breathing events during sleep).	Resonea index (frequency of breathing events during sleep)	N/A	Similar to the predicate device

Description	Subject device Withings Sleep Rx (K231667)	Predicate device Drowzle (K173974)	Reference device EarlySense Bed Sensing Unit (K152911)	Comparison (Similarities/ Differences)
	- Heart Rate - Movement	N/A	- Heart Rate, - Motion - Respiration Rate - Bed occupancy data - Alerts	The subject and reference devices display heart rate and movement during the night. The subject device does not display respiration rate nor provides alerts.
Definition of breathing events	Estimated amount of breathing sound gaps >10 seconds Average number of >10 second breathing sound gaps per hour	Estimated amount of breathing sound gaps >10 seconds Average number of >10 second breathing sound gaps per hour	N/A	Identical to the predicate device
Heart rate range and accuracy	**Range:** 37 - 110 beats per minute **Accuracy as compared to ECG heart rate:** ±5 BPM	N/A	**Range:** 30 - 170 beats per minute **Accuracy as compared to ECG heart rate:** ±4% or ±5 BPM, whichever is greater	The range is different. The subject device labeling warns that the subject device is not intended for users outside the specified range. The accuracy is identical for the subject device and the predicate device for the 37 to 110 beats per minute range and is equal to ±5 BPM.
Accuracy as compared to PSG for AHI ≥ 15	**Withings Index** **Sensitivity:** 88.0% **Specificity:** 88.6% **AUC:** 0.926	**Resonae Index** **Sensitivity:** 93.7% **Specificity:** 63.0% **AUC:** 0.870	**Unknown**	Similar to the predicate device.
Accuracy as compared to PSG for AHI ≥ 30	**Withings Index** **Sensitivity:** 86.0% **Specificity:** 91.2% **AUC:** 0.954	**Unknown**	**Unknown**	No accuracy data has been reported for the predicate device for AHI ≥ 30.
Display type	Companion app display on smartphone or other computing platforms such as tablets.	Smartphone display.	Displayed on a PC monitor using Wireless 2000's proprietary Graphic User Interface (GUI) software. The Central Computer Station (CCS) is typically placed at the nursing station.	Similar to the predicate device.
Reporting method	Results are reported to the clinician and patient within the	Results are reported to the clinician and patient within the	Results are reported to the clinician and patient on the	Similar to the predicate device.

Description	Subject device Withings Sleep Rx (K231667)	Predicate device Drowzle (K173974)	Reference device EarlySense Bed Sensing Unit (K152911)	Comparison (Similarities/ Differences)
	companion app and a PDF format for printing via email	mobile device software and a PDF format for printing via email	EarlySense bedside unit.	
Power source	5 volts	N/A	5 volts	Similar to the reference device
Ways of connection/communication	Bluetooth Low Energy and Wi-Fi	N/A	Communication protocol (RS232) and specific connector	Similar to the reference device. The subject device does not provide serial communication.
Sensor Dimensions	637 x 195 x 24 (inflated) mm^3	N/A	420 X 210 X 14 mm	Similar to the reference device.
Sensor Weight	274 gr.	N/A	760 gr.	Different. The difference in weight does not impact safety nor performance.

Table 1: High-level comparison between the subject device, predicate device and reference device

Withings Sleep Rx (subject device) and Drowzle (predicate device) have the same intended use. Both devices are home-use devices for screening patients with possible sleep disorders.

The technological characteristics of the subject device and the predicate device are different as the subject device uses both an audio sensor and an inflatable bladder with a pressure sensor, while the predicate device is a mobile software that utilizes only the audio sensor of a smartphone. The microphone (audio sensor) of the subject device is embedded into the device to capture breathing sounds. The subject device combines the breathing sounds with pressure changes measured by the pressure sensor to estimate respiratory events indicative of sleep apnea and to then compute the Withings index, whereas the predicate device uses only the breathing sounds to estimate respiratory events indicative of sleep apnea and to compute the Resonae index.

7. Summary of Performance Testing

Non Clinical Testing:
General safety and performance testing was conducted to demonstrate compliance with the FDA guidance documents and recognized standards:

- Software verification and validation was performed per FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".
- Cybersecurity testing was performed per FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions | FDA
- ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R)2012 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility Requirements And Tests

- AAMI TIR69:2017/(R2020) - Wireless coexistence
- ANSI IEEE C63.27-2017 - Wireless coexistence
- FCC testing per part 15

- IEC 60601-1-11: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 62304:2006/Amd 1:2015 - Medical device software
- AAMI/ANSI/IEC 62366-1: Medical Devices – Part 1: Application of Usability Engineering to Medical Devices : 2015
- Human Factors evaluation was conducted per FDA guidance document "Applying Human Factors and Usability Engineering to Medical Devices"
- ISO 14971: Medical Devices – Application of Risk Management to Medical Devices : 2019

Impulse response: A bench test was also conducted to demonstrate that Within Rx capture the changes in impulse response of mattress due to alterations in mattress type and thickness similar to the reference device (i.e., EarlySense Bed Sensing Unit).

Clinical data collected with the subject device

Clinical study for the validation of the Withings' index

To validate the performance of the Withings Index for the screening of OSA, a clinical study was performed (NCT04234828). The subject device was compared with a simultaneous polysomnography (PSG) manually scored by certified specialists, during a single night in a population of 118 patients with suspected obstructive sleep apnea syndrome (OSAS) referred to a PSG test in a sleep laboratory. The performance of breathing events detection by the Withings Index compared to PSG was evaluated using the sensitivity, the specificity, and AUC (Area Under the Curve) with 95% confidence intervals at the PSG-Apnea Hypopnea Index (AHI) threshold values AHI ≥ 15 events/hour and AHI ≥ 30 events/hour. The results of the study were also published in a peer reviewed journal (Edouard P, Campo D, Bartet P, Yang RY, Bruyneel M, Roisman G, Escourrou P. Validation of the Withings Sleep Analyzer, an under-the-mattress device for the detection of moderate-severe sleep apnea syndrome. J Clin Sleep Med. 2021 Jun 1;17(6):1217-1227. doi: 10.5664/jcsm.9168. PMID: 33590821; PMCID: PMC8314651).

Table 2 summarizes the results of the clinical validation study:

	AHI ≥ 15			**AHI ≥ 30**		
	Se	**Sp**	**AUC**	**Se**	**Sp**	**AUC**
Withings' Index Estimated Value	0.88	0.886	0.926	0.86	0.912	0.954
Withings' lower bound of the 95% confidence interval	0.79	0.733	0.873	0.733	0.818	0.916
Acceptance criteria for the 95% confidence interval lower bound	> 0.70	> 0.70	N.A.	> 0.70	> 0.70	N.A.

Table 2: Subject device Withings' Index sensitivity and specificity (and lower bound of the 95% confidence interval) for the classification of apnea severity as compared to the PSG for two PSG-AHI threshold values: AHI ≥ 15 events/hour, and AHI ≥ 30 events/hour. N.A. means not applicable.

The subject device Withings' Index has acceptable sensitivities and specificities for the estimation of breathing events as compared to the PSG for the PSG-AHI threshold values: AHI ≥ 15 events/hour, and AHI ≥ 30 and passed all the acceptance criteria.

Post-hoc Analysis for the validation of the heart rate estimation

A post-hoc analysis was performed using data from two clinical studies that were pooled together to assess the accuracy for the estimation of heart rate (HR). The two clinical studies are:

- ESAS was designed to train the algorithm calculating the Withings index of Sleep Rx, but not to train the estimation of heart rate.
- VPASS was designed to validate the Withings index, but not to train the estimation of heart rate.

Both studies were conducted with the subject device and had the same design, in comparison with simultaneous polysomnography (PSG) scored by a qualified investigator following AASM guidelines. Both studies enrolled patients with a suspicion of sleep apnea syndrome and referred for a sleep study analysis.

Table 3 presents the accuracy for the estimation of heart rate (HR) obtained for the subject device:

Parameter	**Accuracy**	**Lower bound of the 95% confidence interval**	**Acceptance Criteria**
Heart Rate	0.9597	0.9523	Lower bound 95% confidence interval > 0.95

Table 3: Result of clinical studies performed with the subject device for the estimation of heart rate (HR).

These results show that the subject device has a high performance for the estimation of HR with a lower bound of the confidence interval of the accuracy above 0.95 (meeting the acceptance criteria).

Internal human study for the validation of movement detection

An internal study was performed with the subject device to assess its performance for motion detection in conditions simulating movements occurring during sleep.

The co-primary objectives of this study were to assess the subject device's ability to 1) detect movement, 2) separate movements of different energy levels.

The participants performed predetermined movements (of the legs, the arms, and the full body sequentially) for a given duration, separated by quiet intervals. Timestamping of these movements enabled the unambiguous identification of individual movements and the association with the corresponding movement scores during data analysis.

Table 4 provides the performance of the subject device to detect different types of movements:

Endpoint	**Result**	**Acceptance Criteria**

Active / non active Se	0.92 [0.90, 0.94]	> 0.80
Active / non active Sp	0.92 [0.89, 0.94]	> 0.80
Full body / legs AUC	0.94 [0.92, 0.95]	> 0.80
Legs / arms AUC	0.93 [0.91, 0.95]	> 0.80
Arms / no movement AUC	0.89 [0.87, 0.92]	> 0.80

Table 4: Performance (Sensitivity (Se), Specificity (Sp), Area under the Curve (AUC) with 95% confidence intervals) of subject device on binary classifications active / non active, full body / legs, legs / arms, and arms / no movement, with the acceptance criteria and the pass/fail results.

The subject device performance was evaluated by the sensitivity and specificity and was found to pass all the acceptance criteria.

8. Conclusion

The Withings Sleep Rx has the same intended use as the predicate device. In addition, the indication for movement detection and heart rate estimation in a contact-less manner is identical to the reference device. Differences in technological characteristics were assessed through clinical testing to show that the differences do not raise different questions of safety and effectiveness compared to the predicate device. Software verification and validation, non-clinical testing, human factors and clinical study data demonstrate that the Withings Sleep Rx is substantially equivalent to the predicate device.