March 19, 2025

Acurable Limited
Esther Rodriguez-Villegas
CSO
2 Leman Street
London, E1W 9US
United Kingdom

Re: K243092
Trade/Device Name: AcuPebble Ox200
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: February 10, 2025
Received: February 10, 2025

Dear Esther Rodriguez Villegas:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243092

Device Name

AcuPebble Ox200

Indications for Use *(Describe)*

AcuPebble Ox200 is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of adult patients with, or with suspected, obstructive sleep apnea (OSA).The device is primarily intended for home setting use (although can also be used in healthcare settings) under the direction of a Healthcare Professional (HCP).

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

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

510(k) Submitter:	Acurable Limited 2 Leman Street, London E1W 9US, UK
Contact person:	Professor Esther Rodriguez-Villegas CSO Acurable Ltd 20 Victoria Street, SW1H 0NB, London, UK esther@acurable.com +442075946193
Date summary prepared:	18th Mar 2025
Trade Name:	AcuPebble Ox200
Product Classification Name:	Ventilatory effort recorder
Regulation number:	21 CFR §868.2375 (Breathing Frequency Monitor)
Product Code:	MNR
Classification Panel:	Anaesthesiology
Device Classification:	Class II

1. INTENDED USE / INDICATIONS FOR USE

AcuPebble Ox200 is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of adult patients with, or with suspected, obstructive sleep apnea (OSA). The device is primarily intended for home setting use (although can also be used in healthcare settings) under the direction of a Healthcare Professional (HCP).

2. DEVICE DESCRIPTION

AcuPebble Ox200 is prescribed by a Health Care Professional for the patient to use in the home as a 'home sleep apnea test' (HSAT). AcuPebble Ox200 comprises: 1- A small microphones/accelerometer sensor, identical to the one in the previously cleared devices AcuPebble SA100 (K210480) and AcuPebble Ox100 (K222950) that is worn on the front of the neck around the suprasternal notch area (the "AcuPebble SA100 sensor"), and attaches with a single use biocompatible adhesive tape (same one as for "AcuPebble SA100" and "AcuPebble Ox100)); 2- Another PPG/accelerometer sensor ("AcuPebble oximetry sensor") worn either on the finger or on the forehead; 2- A mobile device app (the "AcuPebble Ox200 app") that guides the patient through the steps of the test, collects the data from the sensors, and uploads them in the cloud ; 3- A cloud-based software that analyses the collected signals as in the previously cleared devices; 4- A web app user interface for healthcare professionals where they can set up a study and see the results, including different physiological channel traces and OSA diagnostic parameters, as in the previously cleared devices.

The differences between AcuPebble Ox200 and the previously cleared device (K222950) are:

- A new sensor for sensing the PPG signal and extraction of the SpO2 and pulse rate channel from. This new sensor can be placed either on the finger or the forehead.

- The addition of new parameters extracted from the acoustic neck sensor including position, respiratory efforts and respiratory rate channels.

The OSA diagnostic indexes are still extracted from the signals measured with the identical sensor as in the predicate (neck sensor only), and with the same algorithms, remain unchanged with respect to the predicate device (K222950) and hence have not been separately tested in this device.

3. PREDICATE DEVICE

The predicate device is shown in the Table below:

K number	Product Code	Class	Device Name
K222950	MNR	II	AcuPebble Ox100

The reference devices are shown in the Table below:

K number	Product Code	Class	Device Name
K242798	BZQ	II	Airmod
K240285	MNR	II	Huxley SANSA Home Sleep Apnea Test (1000-00)

4. SUMMARY OF COMPARISON TO PREDICATE

	DEVICE SUBJECT OF THIS APPLICATION **AcuPebble Ox200** K243092, by Acurable Ltd	PREDICATE DEVICE **AcuPebble Ox100**, K222950, by Acurable Ltd	REFERENCE DEVICE (1) **AIRMOD,** K242798, by Heroic Faith International Ltd.	REFERENCE DEVICE (2) **HUXLEY SANSA HOME SLEEP APNEA TEST (1000-00),** K240285, by Huxley Medical	COMPARISON
Indications for use	AcuPebble Ox200 is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of adult patients with, or with suspected, obstructive sleep apnea (OSA).The device is primarily intended for home setting use (although it can also be used in healthcare settings) under the direction of a Healthcare Professional (HCP).	AcuPebble Ox200 is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of adult patients with, or with suspected, obstructive sleep apnea (OSA).The device is primarily intended for home setting use (although it can also be used in healthcare settings) under the direction of a Healthcare Professional (HCP).	Airmod, when used in conjunction with AccurSound Electronic Stethoscope AS-101, is a software as medical device intended to be used for the continuous, non-invasive monitoring of respiratory rate (RR) in adult patients who are subjected to procedural sedation and/or anesthesia. Airmod is intended for use by healthcare professionals in hospitals and healthcare facilities who are legally credentialed to perform procedural sedation and/or anesthesia. Airmod is intended for Android-based devices only	The Huxley Home Sleep Apnea Test (SANSA) is a wearable device intended for use in the recording, analysis, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adults suspected of sleep apnea. The device is intended for the clinical and home use setting under the direction of a Healthcare Professional (HCP).	Same as predicate
Regulation number	868.2375	868.2375	868.2375	868.2375	Same as predicate

Product Code	MNR	MNR	BZQ	MNR/BZQ	Same as predicate
Generic Device Name	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Breathing Frequency Monitor	Ventilatory Effort Recorder/Breathing Frequency Monitor	Same as predicate
Prescription	Prescription	Prescription	Prescription	Prescription	Same as predicate
Target population	Adults	Adults	Adults undergoing procedural sedation and/or anesthesia	Adults (22 years age and older)	Same as predicate
Intended environment for use	Primarily home environment, although it can be used in healthcare environments	Primarily home environment, although it can be used in healthcare environments	Hospitals and healthcare facilities	Clinics and Home Use	Same as predicate
Sensor placement	Front of the neck and either finger or forehead	Front of the neck and finger	Neck	Chest	Same as predicate if placed in finger. If placed in the forehead substantially equivalent. Performance validated as per ISO 80601-2-61:2017.
Physical sensing elements	Piezoelectric (microphones)/ LED+photodiode/accelerometers	Piezoelectric (microphones)/ LED+photodiode/accelerometers	N/A (Software to be used in conjunction with AccurSound Electronic Stethoscope AS-101)	Accelerometer, ECG, Reflectance Photoplethysmography	Same as predicate
Patient contact	Yes	Yes	N/A	Yes	Same as predicate

Means of attachment	Adhesive (patient self-applied)	Adhesive (patient self-applied)	N/A	Adhesive	Same as predicate
Sleep night use	Multiple nights possible	Multiple nights possible	N/A	Multiple nights possible	Same as predicate
Portability	Yes (Wearable)	Yes (Wearable)	N/A	Yes (Wearable)	Same as predicate
Size and weight	29.5mm diameter x 16mm height, 7g weight for neck sensor. 17.25mm x 24.6mm x 12.6 mm, 6g weight for finger/forehead sensor.	29.5mm diameter x 16mm height, 7g weight for neck sensor. 38mm x 30mm x38mm, 15g weight for finger sensor.	N/A	131mmx74mmx11mm, 13g, 60mm x51mm x16mm, 45g	Substantially equivalent. The finger sensor is smaller. This does not pose any new questions of safety and effectiveness.
Recording device	Mobile device records signals streamed from the sensors and uploads them into a cloud-based server	Mobile device records signals streamed from the sensor and uploads them into a cloud-based server	Compatible stethoscope with microphone records acoustic signals	Chest patch sensor record signals then transferred via USB	Same as predicate
Channels	SPO2, PPG, Pulse rate (x2 from PPG and from sounds), activity (movement), heart sounds, respiration inhalation and exhalation patterns, airflow, respiratory effort, respiratory rate, snoring, position	SPO2, PPG, Pulse rate (x2 from PPG and from sounds), activity (movement), heart sounds, respiration inhalation and exhalation patterns, airflow, snoring	Respiratory rate	Oximetry, Heartrate, Chest movement, Snoring, Body position, Respiratory effort, Actigraphy, Sleep stage (Sleep/Wake), ECG (Reference channel only)	AcuPebble Ox200 is substantially equivalent to the predicate device. While AcuPebble Ox200 outputs additional channels compared to the predicate device, these outputs are technologically consistent with those of the reference device. Validation testing has demonstrated that the additional outputs perform

					equivalently to the reference device, and no new questions of safety and effectiveness are raised.
Types of events used for OSA indexes	Apneas/hypopneas	Apneas/hypopneas	N/A	N/A	Same as predicate
Calculated OSA AASM recommended indexes	AHI (with 3% desaturation criteria), AHI (with 4% desaturation criteria)	AHI (with 3% desaturation criteria), AHI (with 4% desaturation criteria)	N/A	SDB	Same as predicate
Diagnostic Sensitivity	92.73% /95.92% (CI- 82.41% to 97.98% /86.02% to 99.50%)	92.73% /95.92% (CI- 82.41% to 97.98% /86.02% to 99.50%)	N/A	88.2% (CI: 81.3% to 93.2%)	Same as predicate
Diagnostic Specificity	96.84% /97.03%	96.84% /97.03%	N/A	87.3% (CI: 82.1% to 91.5%)	Same as predicate
Pulse rate	50-120bpm (3.62bpm validation accuracy from acoustics, Arms < 1.23bpm from PPG)	50-120bpm (3.62bpm validation accuracy from acoustics, Arms 2 bpm from PPG)	N/A	30-250bpm: Arms ≤ 3 bpm	Same as predicate for acoustics. Substantially equivalent for pulse rate to the predicate and this does not raise any new question of safety and effectiveness.

Respiratory rate	4-30 bpm, resolution 1 bpm, accuracy ±3 bpm	N/A	4-35 bpm, ±2.7 bpm	N/A	This is an additional output with respect to the predicate. However, this output is technologically consistent with those of the reference device and validation testing has demonstrated that it performs equivalently to the reference device. Hence no new questions of safety and effectiveness are raised.
Real-time respiratory rate output	No	N/A	Yes (with alarm)	N/A	Same as predicate
Respiratory effort	The accuracy in differentiating between segments with no breathing effort vs with effort (ie what the respiratory effort channels are used in the context of the intended use) is 96.3%. (clinical testing)	N/A	N/A	Non-clinical bench testing.	This is an additional output with respect to the predicate. However, this output is technologically consistent with those of the reference device and validation testing has demonstrated that it is not inferior to the latter. Hence no new questions of safety and effectiveness are raised.
Position	93.93% accuracy in controlled condition and 79.00% accuracy during natural sleep in identifying supine,	N/A	N/A	Using accelerometer, non-clinical bench testing.	This is an additional output with respect to the predicate. However, this output is technologically consistent with those of the reference device

	prone, left, right, and upright position				and validation testing has demonstrated that it is not inferior to the latter. Hence no new questions of safety and effectiveness are raised.
Data Transfer	From the sensor to the mobile phone using Bluetooth and from the phone to the cloud (server) through a smartphone by wireless connection.	From the sensor to the mobile phone using Bluetooth and from the phone to the cloud (server) through a smartphone by wireless connection.	From the compatible stethoscope to the Android mobile phone	Patient data is physically transferred via USB after study conclusion.	Same as predicate
Microcontroller+ Communication chip	Nordic nRF52832 (Bluetooth communication)	Nordic nRF52832 (Bluetooth communication)	N/A	N/A	Same as predicate
Sensor Power Source	Rechargeable lithium ion polymer batteries	Rechargeable lithium polymer battery (neck sensor), and rechargeable lithium ion battery (ring oximeter sensor)	N/A	Rechargeable Lithium Polymer Battery	Same as predicate
Sensor Software	Firmware is limited to control the recording and communications processes. No presentation of OSA test results to the patient. Data analyzed and	Firmware is limited to control the recording and communications processes. No presentation of test results to the patient. Data analyzed and presented in a separate software suite.	N/A	The patient data is physically transferred via USB after study conclusion.	Same as predicate

	presented in a separate software suite.				
Analysis Software - location	Analysis performed off the recording device, exclusively cloud-based, by the proprietary software.	Analysis performed off the recording device, exclusively cloud-based by the proprietary software.	Analysis performed off the recording device	Analysis performed off the recording device, on a compatible cloudbased software platform.	Same as predicate
Display OSA test results	Smartphone (or tablet) or computer screen for healthcare professionals. Smart phone (or tablet) for patients app.	Smartphone (or tablet) or computer screen for healthcare professionals. Smart phone (or tablet) for patients app.	N/A	Software portal where physiological tracings are made available for diagnostic purposes.	Same as predicate
Patient connection	Device has no galvanic connections to mains as it is a battery-operated device.	Device has no galvanic connections to mains as it is a battery-operated device.	N/A	Device has no galvanic connections to mains as it is a battery-operated device.	Same as predicate
Sterilization	Non sterile	Non sterile	N/A	Non sterile	Same as predicate
Biocompatibility	The materials in contact with the body are identical for both the neck and the finger/forehead sensor. The neck sensor is the same as the neck sensor in the predicate.	Contact materials corresponding to the neck sensor and different ones corresponding to the finger sensor.	N/A	The device is considered as a surface device in contact with intact skin per ISO 10993-1. The biocompatibility evaluation was completed and included Cytotoxicity, Sensitization and Irritation testing. All testing passed.	Same as predicate
Duration of contact as	Limited exposure	Limited exposure	N/A	Limited exposure	Same as predicate

per ISO 10993					
Attachment to the body materials	Hypoallergenic acrylate Medical Adhesive	Hypoallergenic acrylate Medical Adhesive Plus: silicon gel and PC (finger)	N/A	Unpublished information	Same as predicate
EMC Testing & Compliance	EN 60601-1-2 (2015) / A1 (2021)	EN 60601-1-2 (2015)	N/A	60601-1-2	Same as predicate
Electrical Safety Testing (Standards Compliance)	EN 60601-1: 2006 + A11: 2011 + A1:2013 + A2:2021 / EN 60601-1-6:2010 + A1:2015 / EN 62366-1:2015 + A1:2020	IEC 60601-1:2006 +A11:2011 +A1:2013	N/A	60601-1	Same as predicate
Home environment testing (Standards Compliance)	IEC 60601-1-11:2015	IEC 60601-1-11:2015	N/A	60601-1-11	Same as predicate
SPO2 testing	ISO 80601-2-61:2017	ISO 80601-2-61:2017	N/A	80601-2-61	Same as predicate

5. PERFORMANCE DATA

Biocompatibility

The materials of both sensors in AcuPebble Ox200 that come in contact with the body are the same as in the previously cleared device K210480. The duration and type of exposure is exactly the same too.

General Requirements for Safety and Electromagnetic Compatibility (EMC)

AcuPebble Ox200 complies with the following recognized consensus standards:

- EN 60601-1: 2006 + A11: 2011 + A1:2013 + A2:2021 / EN 60601-1-6:2010 + A1:2015 / EN 62366-1:2015 + A1:2020- Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- EN 60601-1-2 (2015) / A1 (2021)- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Home Healthcare Environment Safety

AcuPebble Ox200 complies with the following recognized consensus standard:

- IEC 60601-1-11:2015: 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.

Usability

AcuPebble Ox200 complies with the following recognized consensus standards:

- IEC 62366-1 2020- Medical devices-Part 1: Application of usability engineering to medical devices
- IEC 60601-1-6 2020- Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

Risk Management

AcuPebble Ox200 risk management complies with the recognised consensus standard ISO 14971:2019 "Application of risk management to medical devices".

Quality Management

Acurable is ISO 13485:2016 certified by MTIC InterCert SRL.

Software Verification and Validation Testing

AcuPebble Ox100 has been tested and found to comply with the recognized consensus standard IEC 62304:2006/A1:2016 ("Medical device software - Software life cycle processes") and includes "Software integration and integration testing" and "Software system testing" and FDA's software functions guidance

document ("Content of Premarket Submissions for Device Software Functions", June 14, 2023). Furthermore, the cybersecurity risks were addressed according to FDA's cybersecurity guidance document ("Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", September 27, 2023).

Clinical Validation Summary

The performance of the SpO2 and pulse rate output has been validated as per ISO 80601-2-61:2017 by an independent testing lab. The validation was performed on 12 subjects with varying skin tone. The Arms of the OxiPebble SpO2 validated in the range of 70% to 100% was comparable to the predicate, at 1.86 and 2.25 when used on the forehead and on the finger respectively. On the subject whose skin tone was the lightest (Fitzpatrick scale 1 and Monk scale 1), the Arms for the SpO2 is 1.63 and 1.44 when used on the forehead and on the finger respectively. On the subject whose skin tone was the darkest (Fitzpatrick scale 6 and Monk scale 10), the Arms for the SpO2 is 0.66 and 1.36 when used on the forehead and on the finger respectively. For the pulse rate, the average RMSE was found to be 1.23 bpm for both when worn on the forehead and on the finger. The pulse rate output was also tested at the claimed range 50-120 bpm using a functional simulator (Contec SpO2 Simulator MS100, Contec Medical System), where the average RMSE was 0.55 bpm and worst case RMSE was 1.66 bpm.

The respiratory rate has been validated for the 4-30 bpm range in two studies. The first study included 31 healthy subjects. The study was conducted under laboratory conditions against capnography (K150272). The overall RMSD was 2.52 bpm for a range 4-30bpm. The second evaluation was during natural sleep in 150 patients who had been referred for diagnosis of OSA to the Sleep and Ventilation clinic at the Royal Free London Hospital NHS Foundation Trust (Trial registration number: NCT03544086) where the RMSD was 2.46 bpm compared to the chest and abdomen respiratory effort band of Embletta MPR Sleep Data Recording System (K122516). This accuracy and range are comparable to the one of the reference devices (Airmod K2427984. 4-35 bpm, ±2.7 bpm), which also obtained the RR from an acoustic respiratory signal.

The respiratory effort detection has been validated against respiratory inductance plethysmography (RIP) bands during natural sleep in 150 patients referred for OSA diagnosis at the Sleep and Ventilation Clinic at the Royal Free London Hospital NHS Foundation Trust (Trial registration number: NCT03544086).

Based on manual scoring by two clinicians, the agreement in distinguishing between apnoea with no breathing effort versus apnoea with effort was 96.8% when compared to RIP band scoring as the reference.

Furthermore, using automatic scoring from the FDA-cleared device Embla RemLogic (K162140) — which was worn by patients simultaneously — the respiratory effort channel of AcuPebble Ox200 outperformed the reference RIP bands of the Embletta MPR Sleep System (K122516) in identifying segments with breathing effort versus no effort. The accuracy was 96.3% when AcuPebble's respiratory effort channels were used, compared to 75.9% accuracy when the RIP bands were used.

The body position detection has been validated for supine, prone, left, right, and upright positions in two studies:

1. First study: Conducted under laboratory conditions with 17 volunteers, achieving an overall accuracy of 93.93%.
2. Second study: Conducted using data collected during natural sleep from 60 patients referred for OSA diagnosis at Virgen Macarena Hospital, Seville, Spain (Trial registration number:

NCT04028011). The accuracy in this study was 79.00% In detecting supine versus non-supine positions, AcuPebble demonstrated an accuracy of 83.59%.

6. CONCLUSION

The AcuPebble Ox200 is substantially equivalent to the legally marketed predicate device as demonstrated by the similar indication for use, similar technologies and performance data, and does not raise different questions of safety and effectiveness.