February 3, 2023

Acurable Limited
Esther Rodriguez-Villegas
Cso
Finsgate, 5-7 Cranwood Street
London, London EC1V 9EE
United Kingdom

Re: K222950
Trade/Device Name: AcuPebble Ox100
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: December 19, 2022
Received: December 27, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K222950

Device Name

AcuPebble Ox100

Indications for Use *(Describe)*

AcuPebble Ox100 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 settings 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 Finsgate 5-7 Cranwood Street London EC1V 9EE United Kingdom
Contact person:	Professor Esther Rodriguez-Villegas CSO Acurable Ltd 5th Floor, 21 Knightsbridge, London SW1X 7LY, UK esther@acurable.com +442075946193
Date summary prepared:	February 2, 2023
Trade Name:	AcuPebble Ox100
Product Classification Name:	Ventilatory effort recorder
Regulation number:	21 CFR §868.2375 (Breathing Frequency Monitor)
Product Code:	MNR
Classification Panel:	Anesthesiology
Device Classification:	Class II

1. INTENDED USE / INDICATIONS FOR USE

AcuPebble Ox100 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 Ox100 is prescribed by a Health Care Professional for the patient to use in the home as a 'home sleep apnea test' (HSAT). AcuPebble Ox100 comprises: 1- A small physiological sensing device, identical to the previously cleared device AcuPebble SA100 (K210480) 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" too); 2- Another physiological wireless sensing device ("AcuPebble finger oximetry sensor") worn on the finger; 3- A mobile device app (the "AcuPebble Ox100 app") that guides the patient through the steps of the test, collects the data from the sensor (continuously in the case of the "AcuPebble SA100 sensor", and at the end of the test in the case of the "AcuPebble finger oximetry sensor"), and uploads them in the cloud ; 4- A cloud-based software that analyses the signals from the "AcuPebble SA100 sensor" (already cleared as part of K210480); 5- 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. Outputs of the device relevant to its intended use are further described in the comparison table below.

3. PREDICATE DEVICE

The predicate device is shown in the Table below:

K number	Product Code	Class	Device Name
K210480	MNR	II	AcuPebble SA100

4. SUMMARY OF COMPARISON TO PREDICATE AND REFERENCE

	DEVICE SUBJECT OF THIS APPLICATION **AcuPebble Ox100** by Acurable Ltd	PREDICATE DEVICE **AcuPebble SA100,** K210480, by Acurable Ltd	REFERENCE DEVICE **NightOwl**, K191031, by Ectosense	COMPARISON
Indications for use	AcuPebble Ox100 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 SA100 is indicated to sense, record, and interpret a patient's physiological signals (including respiratory pattern) during sleep for the purpose of prescreening patients for obstructive sleep apnea (OSA) syndrome. The device is designed for use in home-screening of adults with suspected possible sleep breathing disorders (although it can also be used in clinic). Results are used to assist the healthcare professional's in the patient's 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 NightOwl is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for the clinical and home setting use under the direction of a Healthcare Professional (HCP).	Substantially equivalent to the predicate and identical to the reference device. This does not raise additional issues of safety or efficacy since AcuPebble Ox100 provides the channels of AcuPebble SA100 and complements this with a PPG based oximetry channel as per the reference device. In the context of the indications for use, the additional channels provided by AcuPebble Ox100 when compared to the reference device: 1- Were already approved as part of AcuPebble SA100; 2- Complement oximetry to aid in the diagnosis of OSA
Regulation number	868.2375	868.2375	868.2375	Same
Product Code	MNR	MNR	MNR	Same
Generic Device Name	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Same
Prescription	Prescription	Prescription	Prescription	Same
Target	Adults	Adults	22 years old and older	Same

population				
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	Clinical and Home environment	Same
Sensor placement	Front of the neck and finger	Front of the neck	Finger	Substantially equivalent. The sensor on the neck allows sensing of physiological signals directly generated by the cardiorespiratory system, in the same way as the predicate. This is in addition to the surrogate signals (blood related features) that are sensed on the finger as in the reference device.
Physical sensing elements	Piezoelectric (microphones)/ LED+photodiode	Piezoelectric (microphones)	Piezoelectric (accelerometer)/LED+photodiode	Substantially equivalent. The optical sensors do not interfere with the other ones and are used to extract SpO2 as in the reference device.
Patient contact	Yes	Yes	Yes	Same
Means of attachment	Adhesive (patient self-applied)	Adhesive (patient self-applied)	Adhesive (patient self-applied)	Substantially equivalent. They both use adhesives and they are both self-applied
Sleep night use	Multiple nights possible	Multiple nights possible	Multiple nights possible	Same
Portability	Yes (Wearable)	Yes (wearable)	Yes (wearable)	Same
Size and weight	29.5mm diameter x 16mm height, 7g weight for neck sensor. 38mm x 30mm x38mm, 15g weight for finger sensor.	29.5mm diameter x 16mm height, 7g weight for neck sensor. 38mm x 30mm x38mm	19x28x11mm, 6g	Substantially equivalent. The sensor on the neck is identical to the one in the predicate. The finger sensor is not in the predicate but the reference device uses a sensor on the finger

				which is comparable to the one in this device in size and weight.
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	Mobile device records signals streamed from the sensor and uploads them into a cloud-based server	Same
Output Channels	SPO2, PPG, Pulse rate (x2 from PPG and from sounds), activity (movement), heart sounds, respiration inhalation and exhalation patterns, airflow (Acoustic derived), snoring	Pulse rate (from sounds), activity (movement), heart sounds, respiration inhalation and exhalation patterns, airflow (Acoustic derived), snoring	SPO2, PPG, Pulse rate, activity (movement)	Substantially equivalent. The additional channels of AcuPebble Ox100 provide extra information that serves to further aid/support in the interpretation and subsequent intervention/management of the disease by a healthcare professional. These channels already appear in other cleared devices, for example the reference device.
Physical sensing elements	Piezoelectric (microphones)/ LED+photodiode	Piezoelectric (microphones)	Piezoelectric (accelerometer)/ LED+photodiode	Substantially equivalent. The optical sensors do not interfere with the other ones and are used in the same way as in the predicate.
Types of events used for OSA indexes	Apneas/hypopneas	Apneas/hypopneas	Apneas/hypopneas	Same
Calculated OSA AASM recommended indexes	AcuPebble_AHI AcuPebble_ODI	AcuPebble_AHI AcuPebble_ODI	NightOwl's AHI	Same as the predicate (the indexes are obtained from acoustic derived physiological biomarkers). In the reference device they are calculated from optically obtained biomarkers (this includes SpO2 obtained from the PPG signal.

Diagnostic LR+	29.36 /32.29	29.36 /32.29	5.10	Same
Diagnostic LR-	0.08 /0.04 (CI- 0.03 to 0.19/0.01 to 0.16)	0.08 /0.04 (CI- 0.03 to 0.19/0.01 to 0.16)	0.04 (CI- 0.01 to 0.17)	Same
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%)	96.55% (CI- 88.09% to 99.58%)	Same
Diagnostic Specificity	96.84% /97.03%	96.84% /97.03%	70.4% to 81.08%	Same
Pulse rate	50-120bm (3.62bpm validation accuracy) when obtained from heart sounds PR from PPG meets the requirement of ±2bpm or ±2%.	50-120bm (3.62bpm validation accuracy) when obtained from heart sounds	50-118bpm (2.26bpm validation accuracy)	Same
SpO2 performance	Compliant with ISO 80601-2-61 80%-100%, 2% root-mean-square difference 70%-79%, 3% root-mean-square difference	Not applicable	Compliant with ISO 80601-2-61, i.e. SpO2 accuracy with a root-mean-square difference of less or equal to 4% over 70-100% SaO2.	Same
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 sensor to the mobile phone using Bluetooth and from the phone to the cloud (server) through a smartphone by wireless connection.	Same
Microcontroller+Communication chip	Nordic nRF52832 (Bluetooth communication)	Nordic nRF52832 (Bluetooth communication)	Nordic nRF52832 (Bluetooth communication)	Same
Sensor Power Source	Rechargeable lithium polymer battery (neck sensor), and rechargeable lithium ion battery (ring oximeter sensor)	Rechargeable lithium polymer battery (neck sensor)	Rechargeable lithium ion polymer battery	Substantially equivalent. Same chemistry, similar capacity, just two batteries (not connected within the same circuits), one for each sensor
Sensor	Firmware is limited to control the recording	Firmware is limited to control the recording	Firmware is limited to control the recording	Same

Software	and communications processes. No presentation of OSA test results to the patient. Data analyzed and presented in a separate software suite.	and communications processes. No presentation of OSA test results to the patient. Data analyzed and presented in a separate software suite.	and communications processes. No presentation of test results to the patient. Data analyzed and 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, exclusively cloud-based by the proprietary software.	Same
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.	Smartphone for patients. For healthcare professionals, one or several of: smartphone (or tablet) or computer screen (unclear which ones)	Same
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.	Device has no galvanic connections to mains as it is a battery-operated device.	Same
Sterilization	Non sterile	Non sterile	Non sterile	Same
Biocompatibility	Assessed to ISO10993-1:2009 requirements for sensitization, irritation and cytotoxicity, and USP class VI	Assessed to ISO10993-1:2009 requirements for sensitization, irritation and cytotoxicity, and USP class VI	Assessed to ISO10993-1:2009 requirements for sensitization, irritation and cytotoxicity	Same

5. PERFORMANCE DATA

Biocompatibility

The enclosure and adhesive of the neck sensor of AcuPebble Ox100 are the same as in the predicate device (K210480).

The enclosure of the finger sensor has undergone biocompatibility testing as per the recognized consensus standard ISO 10993 (Biological Evaluation of Medical Devices) with passing results. Following the principles described in ISO 10993, the device falls into the category of surface-contacting, limited exposure (A) devices. More specifically it is a skin contact device (i.e. a device that contacts skin surfaces only), which is to be used for less than 24h.

General Requirements for Safety and Electromagnetic Compatibility (EMC)

AcuPebble Ox100 complies with the following recognized consensus standards:

- IEC 60601-1:2005:MOD - 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 disturbances - Requirements and tests.

Home Healthcare Environment Safety

AcuPebble Ox100 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.

Risk Management

AcuPebble Ox100 risk management complies with the recognized consensus standard ISO 14971:2019 "Application of risk management to medical devices".

Further information regarding this is included in this submission.

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"), including sections "5.6 Software integration and integration testing" and "5.7 Software system testing". The software for this device was considered as "moderate" level of concern.

Furthermore, the cybersecurity risks were addressed according to FDA's cybersecurity guidance document ("Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", October 2, 2014)

6. CONCLUSION

Based on the performance data and testing in conformance to consensus standards, AcuPebble Ox100 has been demonstrated to be substantially equivalent to the predicate device.