December 21, 2022

Bresotec Inc
Mehrnaz Tabibi
Regulatory and Quality Director
55 York Street Unit 200
Toronto, Ontario M5J 1R7
Canada

Re: K220012
Trade/Device Name: BresoDX1
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: Class II
Product Code: MNR
Dated: November 21, 2022
Received: November 21, 2022

Dear Mehrnaz Tabibi:

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
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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)*

K220012

Device Name

BresoDX1

Indications for Use *(Describe)*

BresoDX1 is indicated for use as an aid in the diagnosis of moderate to severe sleep apnea in adult patients. BresoDX1 records a patient's physiological signals during sleep and scores apneas and hypopneas. BresoDX1 is intended to be used in the home and clinic settings.

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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K220012 - 510(k) SUMMARY

Submitter
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Phone: +1 (647)930-1777
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Contact Person: Mehrnaz Tabibi
Date Submitted: January 4, 2022

Name of Device: BresoDX1

Common or Usual Name: Ventilatory Effort Recorder

Classification Name: 21 C.F.R. 868.2375, Breathing Frequency Monitor

Regulatory Class: II

Product Code: MNR

Predicate Device: ACCUSOM manufactured by NovaSom, Inc. (K110486)

Referenced Devices: WatchPat200U, manufactured by Itamar Medical, Ltd. (K203839), and AcuPebble SA100 manufactured by Acurable Limited (K210480)

Device Description

BresoDX1 is a lightweight data acquisition system intended for use by Health Care Professional (HCP) as an aid in the diagnosis of moderate to severe sleep apnea for adults. It is suitable for independent use in unattended settings, like in the home, or with minimal assistance in clinic settings.

BresoDX1 is to be worn while sleeping and consists of: (1) a BresoSensor which is placed on the patient's suprasternal notch with a disposable BresoSensor Frame (2) a BresoHub, which is located at the bedside; (3) a Nonin WristOx2® pulse oximeter, which is worn on the patient's wrist, where the oximeter sensor is to be placed on the patient's finger; and (4) BresoDX1 software.

The BresoSensor and the Nonin WristOx2® pulse oximeter sensor will record patient's tracheal breathing sounds, neck/body position and movement, tracheo-sternal movement, arterial oxyhemoglobin saturation and heart rate overnight during sleep. Recorded data on the BresoSensor and oximeter will be sent to the BresoHub wirelessly via Wi-Fi and Bluetooth for pre-processing and storing. When the patient returns the BresoDX1 system to the health care professional, stored data that had been uploaded will be processed for analysis and sleep study report generation. The generated report will show the following channels: heart rate, SpO2, airflow, respiratory effort, and body position. The health care professional will be able to use the software to review data, edit automated scoring, and re-generate a sleep study report based on the edited scoring for further interpretation. The health care professional will reprocess the device after each use.

Intended Use / Indications for Use

BresoDX1 is indicated for use as an aid in the diagnosis of moderate to severe sleep apnea in adult patients. BresoDX1 records a patient's physiological signals during sleep and scores apneas and hypopneas. BresoDX1 is intended to be used in the home and clinic settings.

Comparison of Technological Characteristics

Comparison of technological characteristics with predicate and reference devices

	Bresotec's BresoDX1	**NovaSom's ACCUSOM (Predicate)**	**Itamar' s WatchPat200U (Reference Device)**	**AcuPebble SA100 (Reference Device)**	**Comparison**
Regulatory Class, Product Code	**Class II, MNR**	**Class II, MNR**	**Class II, MNR**	**Class II, MNR**	
510k #	**K220012**	**K110486**	**K203839**	**K210480**	
Intended Use / Indications for Use	The BresoDX1 is indicated for use as an aid in the diagnosis of moderate to severe sleep apnea in adult patients. The BresoDX1 records a patient's physiological signals during sleep and scores apneas and hypopneas. The BresoDX1 is intended to be used in the home and clinic settings.	The ACCUSOM device is indicated for use in the diagnostic evaluation of adults with possible sleep apnea. The ACCUSOM can score obstructive apneas, which includes mixed apneas. The ACCUSOM device is intended for use in the home and clinic setting.	The Watch-PAT200U (WP200U) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200U is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP200U generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP200U's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP200U's PSTAGES and snoring level and body position are not	AcuPebble SA100 is indicated to sense, record, and interpret a patient's physiological signals (including 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 (although it can also be used in clinic). Results are used to assist the healthcare professional 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.	Substantially equivalent to predicate device. BresoDX1 does not differentiate between obstructive and mixed apneas. This difference does not impact the ability of BresoDX1 to provide information to the user as an aid in the diagnosis of moderate to severe sleep apnea.

			intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.		
User Population	Home and clinic setting	Home and clinic setting	A non-invasive home care device	For use in home-screening (although it can be used in clinic)	Substantially equivalent to predicate device.
Sensors	-Microphone in BresoSensor placed on the suprasternal notch -Oximeter sensor placed on finger - Three-dimensional accelerometer in BresoSensor placed on suprasternal notch	-Breath Sensor (sensing microphone and ambient noise microphone) placed under the nose -Oximeter finger sensor placed on the finger - Chest Sensor located on the chest.	-uPAT finger probe placed on the finger -Actigraphy on the wrist - (optional) External SBP/RESBP chest sensor (microphone, three-dimensional accelerometer) placed on the chest right under the sternal notch	-Microphone placed on the neck above the suprasternal notch	Substantially Equivalent to predicate device. In addition, BresoDX1 and reference device uses three-dimensional accelerometer.
Channels	Airflow, respiratory effort, tracheal breath sounds tracheo-sternal movement, pulse rate, SpO_2, body position	Airflow, respiratory sounds, pulse rate, SpO_2, snoring level	PAT, pulse rate, oximetry, actigraphy, snoring, body position, chest movement	Sounds (Cardiac features, respiratory features, movement features)	Substantially Equivalent to predicate device. BresoDX1 does not provide the output of snoring levels. Snoring is optional for HSAT and is not essential for the diagnosis of sleep apnea. The difference of system output between BresoDX1 with its predicates does not raise any uncertainty of safety, effectiveness, and efficacy.
Portability	Yes (wearable)	Yes (wearable)	Yes (wearable)	Yes (wearable)	Identical to predicate device.
Data Download	Transfer through wireless connection	Transfer through wireless connection	Transfer through USB connection	Transfer through wireless connection	Substantially equivalent to predicate device.
Size and Weight of sensor	BresoSensor: 17.4×38.7×35.5 mm 17g	Patient Module : 100.3×71.9×29.5 mm 116.2 g	Chest sensor: 1.3inch (32mm) diameter 12g	29.5mm diameter × 16mm height 7g	Different but difference in size and weight do not raise safety or effectiveness question.
Power Source	BresoHub: wall mount power adaptor BresoSensor: Lithium-ion rechargeable battery Oximeter: 2 × 1.5V Alkaline AAA battery	Patient Module: Rechargeable battery operated	One OTS 1.5V Alkaline AAA battery OR One rechargeable AAA 1.2V Nickel-metal hydride battery rechargeable (NiMH) battery	Rechargeable lithium polymer battery	Different but difference in power source do not raise safety or effectiveness question.

Indicators	Visual indicators LEDs on BresoSensor and BresoHub. Indicators on BresoHub Web Interface	Audio and visual indicators	Visual indicator – error messages	N/A	Different. BresoDX1 does not have audio indicators, but it has visual indicators. This difference does not raise safety or effectiveness question.
Sterilization	Nonsterile	Nonsterile	Nonsterile	Nonsterile	Identical.

BresoDX1 and its predicate device, ACCUSOM, utilize the same technology to monitor key signals. Both devices use a microphone to detect a patient's breathing pattern, and a pulse oximeter to determine a patient's arterial oxyhemoglobin saturation and pulse rate. BresoDX1 processes recorded sound data and accelerometer data using a proprietary software algorithm to estimate a subject's airflow changes and respiratory effort and to generate the corresponding waveforms.

Software

BresoDX1 Software collects and stores the data during a test. Data will be uploaded to the cloud. BresoDX1 Software will process and analyze the data to generate a test report. The test report and the data will be reviewed and interpreted by a Health Care Professional.

Some functionalities require connectivity with the cloud system. Those functionalities are as follows:

i. Data upload
ii. Data Storage
iii. Data Analysis
iv. User and Study Management
v. Study Editor
vi. Study Report Generator

The BresoDX1 software is developed according to Medical Device Software/ Software lifecycle processes: IEC 62304:2006/A12016. Also, BresoDX1 software is developed according to Information security, cybersecurity and privacy protection, Information security controls: ISO/ IEC 27002: 2022.

Performance Data

A series of safety and functional testing was performed to confirm that BresoDX1 meets the requirements of the relevant standards. These tests include electrical safety testing according to IEC 60601-1:2005+A1:2012, CAN/CSA-C22.2 No. 60601-1:2014, ANSI/AAMI ES60601-1:2005/A1:2012, home healthcare environment testing according to IEC 60601-1-11:2015, usability according to IEC60601-1-6:2010+A1:2013, application of usability engineering to medical devices according to IEC 62366-1:2015 and IEC 62366-1:2015/COR1:2016, EMC testing according to IEC 60601-1-2:2014, FCC part 15 tests.

Biocompatibility of the patient contacting components (BresoDX1 plastic housing, tape on the BresoSensor Frame) in direct contact with patient's healthy closed skin for up to 8 hours were tested in accordance with ISO10993-1 and FDA's corresponding guidance document, Use of International Standard ISO10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Biocompatibility tests for these patient contacting components of the subject device complaint with the following standards:

- Cytotoxicity per ISO 10993-5 (2009)
- Irritation per ISO 10993-10 (2010)
- Skin sensitization per ISO 10993-10 (2010)

Bench performance tests were performed to demonstrate that the system meets its performance requirements by verifying the device precision and evaluating the inter-device and intra-device repeatability and reproducibility in detecting sleep apnea events and evaluating the impact of environmental noises on the device performance. Oximetry input integration validation test was performed to evaluate the accuracy of the integration of Nonin WristOx2® Model 3150 BLE pulse oximeter with the BresoDX1 system.

All tests confirmed that the subject device meets the pre-determined acceptance criteria and the requirements of the relevant standards.

Clinical performance testing was performed in compliance with the recognized consensus standard ISO 14155:2020 (Clinical investigation of medical devices for human subjects-Good clinical practice to evaluate the capability of BresoDX1. A prospective, single-arm, multiple-site, blinded study was performed to validate the BresoDX1 in comparison with in-laboratory polysomnography (PSG). The study involved overnight recording of the BresoDX1 and clinical PSG in the sleep laboratory, simultaneously. One hundred and sixty-four (164) subjects were evaluated. Based on the clinical performance as documented in the pivotal clinical study, the BresoDX1 has a safety and effectiveness profile that is similar to the predicate device.

The BresoDX1 diagnosis accuracy from the clinical study is summarized as follows:

	REI_b based diagnosis* **n/Total, (95% Confidence Interval)**
Sensitivity	69/78, 88.5% (79.2%, 94.6%)
Specificity	73/86, 84.9% (75.5%, 91.7%)
Positive Predictive Value	69/82, 84.1% (74.4%, 91.3%)
Negative Predictive Value	73/82, 89.0% (80.2%, 94.9%)

* REI_b is the total number of respiratory events scored × 60 divided by monitoring time (in minutes). The diagnostic criteria were based on the established threshold, AHI cut-off 15.

The REI_b accuracy from the clinical study is summarized as follows:

Correlation between REI_b and $AHI_{(PSG)}$ is 0.93

$$AHI_{(PSG)} = 1.033 \times REI_b - 0.0705$$

REI_b is Respiratory Event Index calculated by BresoDX1 software and $AHI_{(PSG)}$ is Apnea and Hypopnea Index calculated by clinical PSG.

The Oxygen Desaturation Index (ODI) accuracy from the clinical study is summarized as follows:

Correlation between $ODI_{(BresoDX1)}$ and $ODI_{(PSG)}$ is 0.95

$$ODI_{(PSG)} = 1.334 \times ODI_{(BresoDX1)} + 5.317$$

$ODI_{(BresoDX1)}$ is Oxygen Desaturation Index calculated by BresoDX1 and $ODI_{(PSG)}$ is Oxygen Desaturation Index calculated by clinical PSG.

SpO2 and Pulse Rate Measurement Accuracy

The accuracy of the Nonin 3150BLE SpO_2 and pulse rate values in comparison to the co-oximeter samples measured over the SpO_2 range of 70% - 100% are validated in accordance with Medical Electrical Equipment- ISO 80601-2-61:2017 Sub-clauses 201.12.1.103 & 201.12.1.104 Pulse Rate and SpO_2 accuracy. Accuracy data is calculated using the root-mean-square (A_{rms} value) for all data points using the following RMS figure of merit calculation:

$$A_{rms} = \frac{\sqrt{\sum_{i=1}^{n}(X_i - X_{Ri})^2}}{n}$$

X_i is the oximeter 4 beat average reading and X_{Ri} is the Oxitest setting at the corresponding sample time.

The accuracy of SpO_2 (A_{rms} value) is ±2% (non-motion, low perfusion) ±3% (motion) within the SpO_2 range of 70% - 100%. The accuracy of pulse rate (A_{rms} value) is ±3% (motion, non-motion, low perfusion) within the pulse rate range of 18-300 BPM (beats per minutes).

Conclusions

BresoDX1 has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate device (K110486). Performance data demonstrated substantially equivalent performance as the ACCUSOM. Thus, BresoDX1 is substantially equivalent to the predicate device.