July 22, 2020

Dymedix Diagnostics, Inc.
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K200654
Trade/Device Name: Rubicon Screening Device
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: June 24, 2020
Received: June 25, 2020

Dear Paul Dryden:

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,

for Michael Ryan
Division Director
DHT1C: Division of ENT, 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 on last page.

510(k) Number *(if known)*

K200654

Device Name

Rubicon Screening Device

Indications for Use *(Describe)*

The Rubicon screening device is a small battery-powered device designed to assess and record nasal and oral airflow in adult patient during sleep in the home setting. The device is intended as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography (PSG) based on the patient's test data.

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

☒ **XX** 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."

Date Prepared: 22-Jul-2020

I Submitter

Dymedix Diagnostics, Inc.
5985 Rice Creek Pkwy.
Shoreview, MN 55126
T – 888-212-1100

Official Contact: Jim Moore, CEO

Submission Correspondent:

ProMedic, LLC
Paul Dryden, President
131 Bay Point Dr. NE
St. Petersburg, FL 33704
E – paul.dryden@promedic.cc
T – 239-307-6061

II Device

Proprietary or Trade Name: Rubicon Screening Device

Common/Usual Name: Ventilatory Effort Recorder

Classification Name: 21CFR 868.2375
MNR – Ventilatory Effort Recorder
Class II

III Predicate Device: K022294– IMS-SleepCheck

Reference Device: K040069 – Dymedix – Airflow Sensor

IV Device Description:

The Rubicon Screening Device is comprised of 3 components and software. For the physical device, Rubicon is comprised of an Airflow sensor, cable connecting air flow sensor and a single inline module (SIM) as described below:

Airflow sensor
The airflow sensor is placed under the user's nose where it converts temperature and pressure changes to a voltage signal. Polarized Polyvinylidene Fluoride (PVDF) is a temperature-sensing material. PVDF generates a small electrical charge in response to temperature change.

The sensor is permanently connected to the SIM via two lead wires.

The temperature difference between patient exhaled air and ambient air, as well as airflow pressure on the sensor generates a small voltage signal, which can be recorded as airflow by recording equipment. The vibration of breath sounds (snoring) produces a small voltage signal, which can be recorded as snoring by recording equipment.

As integrated into the Rubicon, the airflow sensor provides two channels of output data from the same PVDF sensor. One channel focuses on sinusoidal airflow waveforms for identification of airflow events, and the second channel provides snore data.

Cable
The lead wires are a typical cable pair. The lead wires were reviewed as part of the IEC 60601-1 safety evaluation. The lead wires transmit signals from the airflow sensor to the SIM and are permanently attached to the airflow sensor and the SIM.

SIM (Housing and PCB)
The SIM's primary function is to collect raw electrical signals from the airflow sensor. These signals include airflow and snore analog data. These analog signals are filtered and acquired by the SIM's A/D converter, then transmitted in real time to a nearby Smartphone, which must be running the Rubicon companion app. The SIM PCB is powered by a small coin cell battery.

Software
The basic purpose of the software is to:

- Collect data from the sensor device by transmitting the data to a collection hub, which is a Smartphone + a mobile software application (app).
- Transmit data to a remote data center, which is accomplished via the cellular network.
- Store, process, and display data to a health care professional or end user via the Rubicon Analysis Software PC application and its report.

The system consists of three major components: Sim Software (firmware), Rubicon App and Rubicon Desktop Software

V Indications for use:
The Rubicon screening device is a small battery-powered device designed to assess and record nasal and oral airflow in adult patient during sleep in the home setting. The device is intended as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography (PSG) based on the patient's test data.

Patient Population: This device is used only by adults during their sleep

Environments of use: Home settings

The following table presents the comparison to support substantial equivalence.

Table 1 compares the key features of the proposed Rubicon with the identified predicate – K022294– IMS SleepCheck and reference K040069 – Dymedix Air Flow Sensor and demonstrates that this proposed device can be found substantially equivalent.

In summary, one can conclude that substantial equivalence is met based upon the following:

Indications for Use – The Indications for Use are similar. The subject device is only a screening tool which is detecting airflow events based upon airflow characteristics, whereas the predicate also collects airflow data and reports apnea and hypopnea breathing events and is considered a screening tool.

We are not diagnosing but reporting detected airflow events for further consideration by the clinician.

Technology and construction – The technology and construction are similar to predicate in that we are utilizing an airflow sensor to detect breathing events. The employed airflow sensor is identical to the reference, K040069, device which has been cleared for the same intended use. There are no differences in the breathing event detection technology.

The subject device transmits data via BLE to an app. However, transmission of data via wireless technology is not new or novel and does not change the risk profile beyond what is already recognized by FDA as acceptable when applicable testing has been provided.

Environment of Use – The environments of use are similar – home settings.

Patient Population – The patient population is similar to the predicate namely, adults.

Non-Clinical Testing Summary –

Biocompatibility
ISO 10993 designates the sensor as external communicating through tissue contact, and surface contact for a limited duration of use (< 24 hrs.). The cytotoxicity, irritation, sensitization, acute systemic toxicity, and material-mediated pyrogen tests were conducted as per ISO 10993.

Bench testing

Electrical safety, electromagnetic compatibility and comparative performance testing were conducted.

Substantial Equivalence Conclusion -
All testing demonstrated that the proposed device is substantially equivalent to the predicate device.

Table 1

Device Comparison	**Proposed device Rubicon SA system**	**IMS – SleepCheck K022294**	**Reference Dymedix - Sensor K040069**
Classification	MNR Ventilatory Effort Recorder CRF 868.2375	MNR Ventilatory Effort Recorder CRF 868.2375	MNR Ventilatory Effort Recorder CRF 86,2375
Model	Rubicon Screening Device	SleepCheck	Reusable Airflow/Snore Sensor
Indications for Use	The Rubicon screening device is a small battery-powered device designed to assess and record nasal and oral airflow in adult patient during sleep in the home setting. The device is intended as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography (PSG) based on the patient's test data.	The SleepCheck is a small monitor designed to assess nasal and oral airflow. Apnea breathing events are counted based on a reduction in airflow. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score.	The DYMEDIX Airflow Sensor is used with existing recording devices in support of diagnostic recording of nasal, oral airflow and breathing sounds (snore). The sensors are used with patients who require a sleep study.
Target Population	Adult	Adult	Adult
Environment of Use	Home	Home	Home and clinical
OTC or Rx	Rx	Rx	Rx
Design	Main unit Airflow Sensor Single Patient, single use	Main Unit Airflow sensor - pressure Single-Patient, single-use	Air flow sensor measuring temperature changes Reusable
Device Components	Airflow sensor Lead wire SIM with BLE transmission Smartphone app	3 prong cannula with sensors Main unit Data reviewed by clinician	Air flow sensor
Sensor Placement Site	Rests over the lip, under the nose	Rests over the lip, under the nose	Rests over the lip, under the nose
Means of measuring airflow	Airflow sensor has 2 channels, detects changes in airflow and noise (snoring) which is converted to a voltage signal	Airflow sensor	Air flow sensor has 2 channels, detects changes in air flow and noise (snoring) which is connected to a recorder

Device Comparison	**Proposed device** **Rubicon screening**	**IMS – SleepCheck** **K022294**	**Reference** **Dymedix - Sensor K040069**
Measures snoring	Yes	No	Yes
Measures	Airflow events	Apnea Hypopnea	No
Calculation of Airflow event	Signal decrease of 10 sec. or longer	Signal decrease of 10 sec. or longer	Sensor only
Records and Presents data	Airflow events (AFE) AFE Index Estimated Sleep Time Estimated Sleep Efficiency This is a screening tool only	Apnea and Hypopnea AHI Total apnea events Numeric readout Breathing indicator – moving bar display This is a screening tool only	Sensor only
Data transmission	Bluetooth between SIM and Smartphone	Data viewed by clinician	Sensor only
Specifications			Sensor only
Sampling rate	Respiratory flow and breathing sounds: 100 Hz	10 Hz	
Nights of monitoring	Up to 2	Single night	
Power source	Battery – coin sized 20-hour maximum usage (2 tests)	Alkaline battery	
Dimensions of main unit	Width: 114mm Height: 70mm Depth: 25mm	Small wearable main unit	
Safety and EMC	ES 60601-1 IEC 60601-1-2 IEC 60601-1-11	ES 60601-1 IEC 60601-1-2 EC 60601-1-4	
Biocompatibility	Airflow sensor considered Externally communicating and Surface contact Limited duration testing	Airflow sensor considered Externally communicating and Surface contact Limited duration testing	
Comparative testing	Data and scoring compared to PSG collected and analyzed data and reviewed by independent sleep specialists	PSG comparison	