DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 9, 2017

Respiratory Motion, Inc.
Susan Hamann
Director of Quality and Regulatory
411 Waverly Oaks Road, Building 1, Suite 150
Waltham, Massachusetts 02452

Re: K162131
Trade/Device Name: ExSpiron™ 1Xi
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: Class II
Product Code: BZK, BZQ
Dated: April 5, 2017
Received: April 10, 2017

Dear Susan Hamann:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162131

Device Name
ExSpiron 1Xi

Indications for Use *(Describe)*
ExSpiron 1Xi is indicated for use by healthcare professionals in healthcare facilities, such as post-operative care and critical care units, to monitor breathing in adult (at least 21 years old) patients.
ExSpiron 1Xi is a non-invasive monitor that graphically displays lung volume against time and reports an approximate value of:
* Minute Ventilation (MV)
* Tidal volume (TV)
* Respiratory rate (RR)
ExSpiron 1Xi measurements are used as an adjunct to other clinical information.

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.

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"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 – Traditional 510(k)

510(k) Owner:	Respiratory Motion, Inc.
Address:	411 Waverley Oaks Road Building 1, Suite 150 Waltham, Massachusetts 02452
Phone:	781-373-1636
Fax:	781-373-1653
Contact person:	Jenny Freeman, MD
Date 510(k) Summary prepared and type of 510(k):	May 9, 2017 – Traditional 510(k)
Trade name:	ExSpiron ™ 1Xi
Common name:	Respiratory Monitoring System
Classifications:	Regulation Number: 21 CFR 868.1850 Regulation Name: Monitoring Spirometer Regulatory Class: II Product Code: BZK, BZQ
Predicate devices:	ExSpiron 1Xi Respiratory Monitor, marketed by Respiratory Motion, Inc, Waltham, MA (K130170).
Device Description:	The ExSpiron 1Xi is a noninvasive respiratory monitoring system that graphically displays lung volume against time and reports Minute Ventilation, Tidal Volume and Respiratory Rate. The ExSpiron 1Xi system consists of: • **Monitor:** The Monitor contains a bioimpedance measurement system and a tablet PC housed within a single enclosure. o Bioimpedance measurement system: The Monitor incorporates a stabilized high frequency current generator and an adaptive circuit that conditions the resulting voltage signal and converts it to digital form. Firmware within the Monitor performs signal acquisition and relays data to the tablet PC. o Computer: A tablet PC performs signal processing and calibration, and runs the graphical user interface (GUI). The PC takes user input from a touch screen through a virtual keyboard and mouse. The GUI is used for recording patient data and displaying the respiratory trace as well as scalar values and trends for minute ventilation, tidal volume, and respiratory rate. • **Single-Patient Use ExSpiron Electrode PadSet :**

	A Single-Patient Use Electrode PadSet is placed on the skin of the patient's torso. It delivers current to, and records impedance measurements from, the skin. The Electrode PadSet for the ExSpiron 1Xi is identical to that cleared for the Predicate device.
Intended use:	ExSpiron 1Xi is indicated for use by healthcare professionals in healthcare facilities, such as post-operative care and critical care units, to monitor breathing in adult (at least 21 years old) patients. ExSpiron 1Xi is a non-invasive monitor that graphically displays lung volume against time and reports an approximate value of: * Minute Ventilation (MV) * Tidal volume (TV) * Respiratory rate (RR) ExSpiron 1Xi measurements are used as an adjunct to other clinical information.

Comparison of technological characteristics:

Characteristic	ExSpiron 1 (Proposed Device)	ExSpiron™1Xi (Predicate) K130170	Comment
Intended Use	ExSpiron 1Xi is indicated for use by healthcare professionals in healthcare facilities, such as post-operative care and critical care units, to monitor breathing in adult (at least 21 years old) patients Each ExSpiron 1Xi is a noninvasive system that graphically displays lung volume against time and reports an approximate value of: • Tidal volume • Respiratory rate, and • Minute ventilation. ExSpiron 1Xi measurements are used as an adjunct to other clinical information sources.	ExSpiron 1Xi is indicated for use by healthcare professionals in healthcare facilities, such as post-operative care and critical care units, to monitor breathing in adult (at least 21 years old) patients Each ExSpiron 1Xi is a noninvasive system that graphically displays lung volume against time and reports an approximate value of: • Tidal volume • Respiratory rate, and • Minute ventilation. ExSpiron 1Xi measurements are used as an adjunct to other clinical information sources.	Both the proposed device and the predicate have an identical intended use.
Technology	Measurement is by thoracic bioimpedance.	Measurement is by thoracic bioimpedance.	Both the proposed device and the predicate have identical technology.
Volume Measurements	Tidal volume Minute volume Volume vs. time chart	Tidal volume Minute volume Volume vs. time chart	Both the proposed device and the predicate measure the same respiratory volumes.
Rate Measurements	Respiratory rate (breaths/min)	Respiratory rate (breaths/min)	Both the proposed device and the predicate measure respiratory rate.
Safety	IEC 60601-1, including electrical and mechanical safety	IEC 60601-1, including electrical and mechanical safety	Both the proposed device and the predicate have the same electrical safety profile and are compliant with IEC 60601-1.
Energy Source	The bioimpedance output signal is generated internally to the ExSpiron Monitor. It is a low current signal at approximately 50 kHz.	The bioimpedance output signal is generated internally to the ExSpiron Monitor. It is a low current signal at approximately 50 kHz.	Both the proposed device and the predicate have the same energy source.

Algorithm	A software algorithm calculates respiratory parameters using a proprietary, non-linear, regressive model trained with a dataset containing respiratory data from a large historical cohort. The algorithm was refined for the ExSpiron 1Xi- using thousands of additional data points collected over the last 3 years in a wide variety of patient populations. With the additional training data, the algorithm now provides accurate respiratory volumes without patient-specific calibration.	A software algorithm calculates respiratory parameters using a proprietary, non-linear, regressive model trained with a dataset containing respiratory data from a large historical cohort.	Both the proposed device and the predicate have essentially the same firmware, except the proposed device has been refined with thousands of additional data points that result in a more accurate estimate of respiratory parameters than the predicate.
Enclosure	Formed plastic (ABS) housing, flame-retardant.	Formed plastic (ABS) housing, flame-retardant.	Both the proposed device and the predicate have the same enclosure material.
EMC/EMI Compliance	IEC 60601-1-2 compliant	IEC 60601-1-2 compliant	Both the proposed device and the predicate are 60601-1-2 compliant.
Electrode PadSet	Single-patient use, biocompatible, printed padset.	Single-patient use, biocompatible, printed padset.	Both the proposed device and the predicate use the same electrode padset.
Impedance Measurement Range	15 Ohms to 180 Ohms	15 Ohms to 180 Ohms	Both the proposed device and the predicate have the same measurement range.
Tablet Computer	Windows tablet computer.	Windows tablet computer.	Following FDA clearance of the predicate (K130170), a "letter to file" change was made to substitute an equivalent Windows tablet computer in the device (See "Letter to File" changes; Section 21b in this 510(k) filing).
Biocompatibility	Neither the Monitor nor the Patient Cable are intended for patient contact. The Electrode PadSet is biocompatible.	Neither the Monitor nor the Patient Cable are intended for patient contact. The Electrode PadSet is biocompatible.	Both the proposed device and the predicate have identical biocompatibility.
Usability	ISO 60601-1-6 compliant	ISO 60601-1-6 compliant	Both the proposed device and the predicate have the same usability when used in the Volume Synchronization and Percent Baseline modes of operation. In the Basic Monitoring mode that has been introduced in the proposed device, the calibration step that was required for the predicate device has been eliminated.
Accuracy	MV - 11.5% TV - 11.4% RR - 0.1%	MV - 10.7% TV - 10.4% RR - 2.0%	Details of the accuracy of the proposed device versus the predicate are included in Section 20: Performance Testing - Clinical.

Nonclinical testing:

Nonclinical testing was performed to demonstrate the equivalence of the ExSpiron 1Xi to the predicate. The FDA recognized tests that were completed are listed below. See Section 9.0; Declarations of Conformity and Summary Reports for details of the testing.

- Basic Safety and Essential Performance (IEC 60601-1; Ed. 3.0) - Pass,
- Immunity/Emissions (IEC 60601-1-2; Ed. 3.0) - Pass,
- Usability (IEC 60601-1-6; 2010, A1:2013 and 62366;2007, A1:2014) - Pass, and
- Alarms (IEC 60601-1-8; 2006) - Pass.

Other tests which are not FDA recognized were also completed. The following non-FDA recognized tests were performed and each achieved favorable results:

- Degrees of protection provided by enclosures (IEC code) (IEC 60529; 2004)
- Packaged products weighing 150 lbs (68 kg) or less (ISTA Procedure 1A; 2014)
- ECG Trunk Cables and patient lead wires (ANSI EC53; 2013)
-

The results of this testing demonstrate that the proposed device is equivalent to the predicate in safety and essential performance.

Clinical performance testing:

A clinical study was conducted in Waltham MA, USA to compare simultaneous measurements from the ExSpiron 1Xi and the predicate device. Twenty subjects representing a broad range of intended patients participated in the study. (Age range: 22-80, BMI range: 19-42 with 9 female, 11 male). The study involved two sessions for each subject, an initial session in which electrodes were applied and each subject performed twenty breathing tests. Tidal volume, minute ventilation, and respiratory rate were measured and processed by both the Predicate and the Proposed device. Each subject returned twenty-four hours after the first session with the original electrodes still attached. A second set of twenty breathing tests were performed.

The results of the clinical study were:

Proposed ExSpiron 1Xi /Predicate ExSpiron 1Xi Comparison		**Minute Ventilation**	**Tidal Volume**	**Respiratory Rate**
Bias	**Overall**	**2.2%**	**2.2%**	**0.01%**
	Day 1	3.4%	3.4%	0.02%
	Day 2	1.1%	1.1%	0.00%
Precision	**Overall**	**7.0%**	**6.9%**	**0.08%**
	Day 1	5.2%	5.1%	0.11%
	Day 2	5.1%	5.1%	0.00%
Accuracy	**Overall**	**11.5%**	**11.4%**	**0.08%**
	Day 1	10.1%	10.1%	0.11%
	Day 2	12.3%	12.3%	0.00%

The results indicate clinically relevant accuracy over a 24-hour period.

Conclusions regarding safety and effectiveness:

Based on the comparison of the intended use of the predicate and the proposed device, and on the results of nonclinical and clinical testing, the proposed ExSpiron 1Xi is substantially equivalent to the predicate and is as safe and as effective as the predicate.