



March 16, 2018

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

Re: K173181
Trade/Device Name: ExSpiron™ 1Xi
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: Class II
Product Code: BZK, BZQ
Dated: February 8, 2018
Received: February 12, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Tina Kiang
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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

Indications for Use

510(k) Number (if known)
K173181

Device Name ExSpirom 1Xi

Indications for Use (Describe)

ExSpirom 1Xi is indicated for use by healthcare professionals in healthcare facilities, such as post-operative care and critical care units, to monitor breathing in patients at least one year of age.

ExSpirom 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)

ExSpirom 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.

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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):	March 15, 2018 – 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 (K162131).
Reference Device	The Philips NM3 was chosen as a reference device in the clinical study because it measures the same parameters as the ExSpiron 1Xi in a continuous and non-invasive manner, comparable to our device.
Device Description:	<p>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.</p> <p>The ExSpiron 1Xi system consists of:</p> <ul style="list-style-type: none"> • Monitor: The Monitor contains a bioimpedance measurement system and a tablet PC housed within a single enclosure. <ul style="list-style-type: none"> ○ 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. ○ 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

	<p>and displaying the respiratory trace as well as scalar values and trends for minute ventilation, tidal volume, and respiratory rate.</p> <p>There are no hardware changes included in this submission.</p> <ul style="list-style-type: none">• 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:	<p>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 patients at least one year of age.</p> <p>ExSpiron 1Xi is a non-invasive monitor that graphically displays lung volume against time and reports an approximate value of:</p> <ul style="list-style-type: none">* Minute Ventilation (MV)* Tidal volume (TV)* Respiratory rate (RR) <p>ExSpiron 1Xi measurements are used as an adjunct to other clinical information.</p>

Comparison of technological characteristics:	Characteristic	ExSpiiron 1Xi with Pediatric (Proposed Device)	ExSpiiron™1Xi (Predicate) K162131	Comment
	Intended Use	<p>ExSpiiron 1Xi is indicated for use by healthcare professionals in healthcare facilities, such as post-operative care and critical care units, to monitor breathing in patients at least 1-year of age.</p> <p>ExSpiiron 1Xi is a non-invasive monitor that graphically displays lung volume against time and reports an approximate value of:</p> <ul style="list-style-type: none"> • Minute Ventilation (MV) • Tidal volume (TV) • Respiratory rate (RR) <p>ExSpiiron 1Xi measurements are used as an adjunct to other clinical information sources.</p>	<p>ExSpiiron 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.</p> <p>ExSpiiron 1Xi is a non-invasive monitor that graphically displays lung volume against time and reports an approximate value of:</p> <ul style="list-style-type: none"> • Minute Ventilation (MV) • Tidal volume (TV) • Respiratory rate (RR) <p>ExSpiiron 1Xi measurements are used as an adjunct to other clinical information.</p>	<p>The proposed device has a new indication for use. Patient populations will be expanded to include pediatric patients at least 1-year old.</p>
	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 ExSpiiron Monitor. It is a low current signal at approximately 50 kHz.	The bioimpedance output signal is generated internally to the ExSpiiron 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.	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 the same algorithm.
	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.

Graphical User Interface	Graphical User Interface allowed input of demographic patients at least 1 year of age.	Graphical User Interface allowed input of demographic patients at least 21 years of age.	Both the proposed device and the predicate have the same hardware, firmware, and core software functionality. The proposed device has several changes to the GUI as well as disabling of the “Basic Monitoring” functionality when used for pediatric patients since this functionality has not been validated in this population.
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.	Both the proposed device and the predicate use the same tablet computer.
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. Basic Monitoring is disabled in Pediatric Mode.
Accuracy	MV - 11.9% TV - 12.0% RR – 4.2%	MV - 11.5% TV - 11.4% RR - 0.1%	Details of the accuracy of the proposed device versus the predicate are included in the Clinical. Performance section of this summary.

<p>Nonclinical testing:</p>	<p>Nonclinical testing was performed to demonstrate the equivalence of the ExSpirom 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.</p> <ul style="list-style-type: none"> - 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. <p>Other tests which are not FDA recognized were also completed. The following non-FDA recognized tests were performed and each achieved favorable results:</p> <ul style="list-style-type: none"> - 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) - <p>The results of this testing demonstrate that the proposed device is equivalent to the predicate in safety and essential performance.</p>
<p>Clinical performance testing:</p>	<p>The device was tested on pediatric patients in a prospective observational study at Children’s Hospital of Boston.</p> <p>The aim of this study was to evaluate the capability of the ExSpirom 1Xi to accurately measure tidal volume (TV), minute volume (MV), and respiratory rate (RR) in the perioperative setting in pediatric patients who were intubated and undergoing general anesthesia.</p> <p>We studied pediatric patients between the ages of 1 year and 17 years, ASA status I to III scheduled to undergo a surgical procedure under general anesthesia at Boston Children’s Hospital.</p> <p>Continuous respiratory data were collected simultaneously from the ExSpirom 1Xi and a monitoring spirometer placed in the respiratory circuit (NM3, Respiromics NM3 Respiratory Profile Monitor, Philips Healthcare, Amsterdam, Netherlands). Both the ExSpirom 1Xi and NM3 provide real-time measurements of MV, TV, and RR.</p> <p>Data from 72 pediatric patients show the ExSpirom 1Xi mean measurement bias (ExSpirom 1Xi – NM3 measurement) for MV was –3.8% (95% limits of agreement) (+/-1.96 SD): (-19.9% to 12.2%), for TV it was –4.9 (-21.0% to 11.3%), and for RR it was 1.1% (-4.1% to 6.2%). The mean measurement accuracy errors for MV, TV, and RR were 11.9%, 12.0%, and 4.2% (0.6 breaths/min), respectively. Note that, lower accuracy values indicate higher measurement agreement. The equivalence tests rejected the null hypothesis that the ExSpirom 1Xi and NM3 have different mean values and conclude with 90% power that the measurements of MV, TV, and RR from the ExSpirom 1Xi and NM3 are equivalent within +/-10%. These data demonstrate agreement between ExSpirom 1Xi and NM3 measurements in the studied pediatric population.</p>
<p>Conclusions regarding safety and effectiveness:</p>	<p>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 ExSpirom 1Xi (Pediatric) is substantially equivalent to the predicate and is as safe and as effective as the predicate.</p>