December 17, 2019

Respiratory Motion, Inc.
Susan Hamann
Director of Quality and Regulatory
80 Coolidge Hill Road
Watertown, Massachusetts 02472

Re: K192595
Trade/Device Name: ExSpiron 2Xi
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: Class II
Product Code: BZK, BZQ
Dated: December 2, 2019
Received: December 3, 2019

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. 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 below.

510(k) Number *(if known)*
K192595

Device Name
ExSpiron 2Xi

Indications for Use *(Describe)*
ExSpiron 2Xi 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.

ExSpiron 2Xi 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 2Xi 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 – Special 510(k)
K192595

510(k) Owner:	Respiratory Motion, Inc.
Address:	80 Coolidge Hill Road Watertown, MA USA 02472
Phone:	781-373-1636
Fax:	781-373-1653
Contact person:	Jenny Freeman, MD
Date 510(k) Summary prepared and type of 510(k):	December 12, 2019 Special 510(k)
Trade name:	ExSpiron 2Xi
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, Watertown, MA (K173181).
Device Description:	The ExSpiron 2Xi Respiratory Monitor System consists of: Monitor: The Monitor contains a bioimpedance measurement system and a tablet PC housed within a single enclosure. 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 and displaying the respiratory trace as well as scalar values and trends for minute ventilation, tidal volume, and respiratory rate. Patient Cables and Electrode Padsets that are also included in the system but were cleared in previous 510(k)s: K130170, K162131, K173181 ExSpiron Patient Cable: A reusable cable that connects the ExSpiron 2Xi Monitor to the Electrode PadSet. 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.
Intended use:	ExSpiron 2Xi is indicated for use by healthcare professionals in healthcare facilities, such as postoperative care and critical care units, to monitor breathing in patients at least one year of age. ExSpiron 2Xi 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 2Xi measurements are used as an adjunct to other clinical information.

Special 510(k) Summary Continued

Comparison to cleared device

Characteristic	ExSpiron® 2Xi Proposed Device	ExSpiron® 1Xi (Predicate) (K173181)	Comment
Intended Use	ExSpiron 2Xi is indicated for use by healthcare professionals in healthcare facilities, such as postoperative care and critical care units, to monitor breathing in patients at least one year of age. ExSpiron 2Xi 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 2Xi measurements are used as an adjunct to other clinical information.	ExSpiron 1Xi is indicated for use by healthcare professionals in healthcare facilities, such as postoperative care and critical care units, to monitor breathing in patients at least one year of age. 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.	Both the proposed device and the predicate have identical Intended Use
Technology	Measurement is by thoracic bioimpedance.	Measurement is by thoracic bioimpedance.	Both the proposed device and the predicate have identical fundamental scientific 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 an equivalent 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 equivalent energy source.
Power Management Board	Board is external to the tablet computer.	Board is internal to the tablet computer.	Functionality of Power Management Board remains unchanged. The two boards are substantially equivalent.
Data Acquisition Board	Digital Data Acquisition Board.	Analog Data Acquisition Board.	Updated Data Acquisition Board performs the same core functions as the predicate along with built in Nurse Call Circuitry and additional electric isolation. Safety and effectiveness of differences have been addressed

			through relevant performance testing.
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 fundamental algorithm
Enclosure	Injection molded plastic (ABS) housing, flame-retardant.	Formed plastic (ABS) housing, flame-retardant.	Both the proposed device and the predicate have equivalent 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 1 year of age.	The Graphical User Interface is different in the proposed device owing to the different size of tablets used in the devices, however the content is equivalent.
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	Linux tablet computer.	Windows tablet computer.	The proposed device and the predicate use different tablet computers. The functions of the tablet remain the same.
Nurse Call Relay	Nurse call relay is contained within the monitor.	Nurse call relay module is an accessory to the monitor.	A nurse call relay has been integrated into the monitor in the proposed device. Performance testing was conducted to demonstrate substantial equivalence.
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 are biocompatible.
Usability	IEC 60601-1-6 compliant	IEC 60601-1-6 compliant	Usability Testing was performed to demonstrate that the 2Xi is equivalent to the 1Xi when used by intended users in the intended environment.

Bench Accuracy	MV 1.57% TV - 2.28% RR - 1.55%	MV 1.78% TV - 2.39% RR - 1.38%	The accuracy of the proposed device is substantially equivalent to the predicate.

Additional Information:

Summary of Performance and Bench Testing Performed – All the testing passed the verification and validation requirements. The list of tests performed is as follows:

1. Software Test Protocol
2. Accuracy Test Protocol
3. System Power Verification Test
4. System Battery Verification Test
5. Internal Usability Testing
6. Nurse Call Test
7. User Manual Verification Test
8. Do by Analysis Test - This tests requirements that need static analysis, calculations, and visual inspection.

Summary of Clinical Testing performed –Design changes to device were confirmed and validated by performance and bench testing. Clinical testing was not required.

Summary of Biocompatibility testing - Additional testing was not required for the ExSpiron 2Xi. The Padset and cables are identical to previous submissions for the ExSpiron 1Xi. The monitor and patient cables are not intended for patient contact.

Conformance to Standards applicable to the device – The ExSpiron 2Xi met the applicable requirements specified in the standards. The standards used are:

1. ANSI AAMI IEC 60601-1:2005/(R)2012 And A1:2012 (Consolidated Text)
2. ANSI AAMI IEC 60601-1-2:2014
3. ANSI AAMI IEC 60601-1-8:2006/AMD1:2012
4. ANSI AAMI IEC 60601-1-6:2010/AMD1:2013
5. ANSI AAMI IEC 62304:2006/A1:2016
6. ANSI AAMI IEC 62366-1:2015
7. ANSI AAMI ISO 14971:2007/(R)2010 (Corrected 4 October 2007)
8. ANSI AAMI IEC 62133-2:2017

Conclusion: Based on the testing and evaluations performed on the ExSpiron 2Xi, the device is as safe, as effective, and is substantially equivalent to the predicate device.