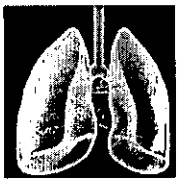
K120087

SEP 26 2012



510(k) Summary

510(k) Owner:	Respiratory Motion, Inc.
Address:	305 Second Avenue, Suite B Waltham, Massachusetts 02451
Phone:	781-373-1636
Fax:	781-373-1653
Contact person:	Jenny Freeman, MD
Date 510(k) Summary prepared:	September 20, 2012
Trade name:	ExSpiron™
Common name:	Respiratory Monitor
Classifications:	Monitoring spirometer Product code: BZK Regulation: 21 CFR 868.1850 Breathing frequency monitor Product code BZQ Regulation: 21 CFR 868.2375
Predicate devices:	For product code BZK, nSpire Wright/Haloscale Respirometer, marketed by nSpire Health, Inc. of Longmont, CO 510(k) K091853 For product code BZQ, Philips MPn0 Intellivue Patient Monitors, marketed by Philips Healthcare 510(k) K060541
Device Description:	The ExSpiron™ consists of: • **Bioimpedance measurement system**: A stabilized high frequency current generator is connected to two outer electrodes. The inner four electrodes are connected to an adaptive circuit that conditions the resulting voltage signal and converts it to digital form. Firmware performs signal acquisition and relays data to the panel PC. • **Panel PC**: A Windows 7 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 volume, tidal volume, and respiratory rate. • **Single Patient Use ExSpiron™ Electrode Lead Set:** An electrode lead set containing six electrodes to be placed on the torso. It delivers current and records impedance measurements. The electrode lead set is also used to perform subsystem checks prior to patient measurements.

Intended use:

ExSpiron™ 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™ is a non-invasive system that graphically displays lung volume against time and reports an approximate value of:

- Tidal volume,
- Respiratory rate, and
- Minute ventilation

ExSpiron™ measurements are used as an adjunct to other clinical information sources.

Comparison of technological characteristics:

Characteristic	ExSpiron™	nSpire	Philips Intellivue Monitor	Comment
Intended Use	See above.	See K091853	See K060541	The clinical application of the ExSpiron™ is equivalent to that of the nSpire. The comparison to the intended use of the Philips monitor is restricted to monitoring of respiration rate. ExSpiron™ has no alarm function. All devices are used by healthcare professionals.
Technology	Measurement is by thoracic bioimpedance.	Measurement is by in-line turbine flow meter.	Measurement is by bioimpedance.	
Volume Measurements	Tidal volume Minute volume Volume vs. time chart	Tidal volume Minute volume	None	The time function for the minute volume measurement of the nSpire is provided by a user's stopwatch.
Rate Measurements	Respiratory rate (breaths/min)	None	Respiratory rate	
Safety	IEC 60601-1, including electrical and mechanical safety	Mechanical only. Safety specifications are not given in the user manual or 510(k) summary.	IEC 60601-1, etc.	

Nonclinical performance testing:

Performance testing confirmed essential performance by IEC 60601-1 and IEC 60601-1-2 tests and confirmed usability by simulated use by physicians and nurses representative of intended users.

Clinical performance testing:

A clinical study compared simultaneous measurements from the ExSpiron and the predicate, Wright spirometer. (Respiratory rate was calculated using a stop watch.) Twenty subjects representing a broad range of intended patients participated in the study. (Age range: 20-84, BMI range: 19.9-43.2, 11 female, 9 male) The study involved two sessions for each subject, an initial session in which electrodes were applied, the ExSpiron was calibrated to the individual, and each subject performed ten 60-second breathing tests. Tidal volume, minute ventilation, and respiratory rate were measured simultaneously by the ExSpiron and the Wright spirometer. Each subject returned twenty-four hours after the first session with the original electrodes still attached. Using the same individual calibration values, a second set of ten 60-second breathing tests was performed.

The results of ExSpiron-Wright study were:

ExSpiron-Wright		Minute Ventilation	Tidal Volume	Respiratory Rate
Bias	**Overall**	**-2.1%**	**-1.9%**	**-0.2%**
	Day 1	-2.3%	-1.7%	-0.6%
	Day 2	-1.9%	-2.0%	0.2%
Precision	**Overall**	**10.5 %**	**10.3 %**	**2.0 %**
	Day 1	10.2%	9.7%	2.3%
	Day 2	10.8%	10.8%	1.6%
Accuracy	**Overall**	**10.7 %**	**10.4 %**	**2.0 %**
	Day 1	10.4%	9.8%	2.4%
	Day 2	10.9%	11.0%	1.6%

The results indicate that the individual calibration is stable over a 24-hour period.

A similar study was performed comparing the Wright spirometer to the Morgan SpiroAir LT diagnostic spirometer. (The closed cell construction of the Morgan spirometer limits the breathing test time to 30 seconds. A direct comparison of the ExSpiron to the Morgan spirometer is suboptimal.) A different set of twenty subjects participated. (Age range: 20-60, BMI range: 19.0-28.0, 9 female, 11 male) Each subject participated in one session performing twenty 30-second breathing tests with volume measurements made simultaneously with the Wright spirometer and the Morgan diagnostic spirometer.

The Morgan-Wright study results were:

Wright-Morgan	Minute Ventilation	Tidal Volume
Bias	**0.4%**	**0.4%**
Accuracy	**3.9%**	**3.9%**

Continued on next page.

<table>
<tr><td>Clinical performance testing:
Continued from previous page</td><td>Combining the results of the ExSpiron-Wright study and the Wright-Morgan study provided calculated estimates of ExSpiron bias and accuracy with respect to the Morgan diagnostic spirometer:
<table><tr><th>ExSpiron-Morgan</th><th>Minute Ventilation</th><th>Tidal Volume</th></tr><tr><td>Bias</td><td>-1.7%</td><td>-1.5%</td></tr><tr><td>Accuracy</td><td>9.9%</td><td>9.6%</td></tr></table></td></tr>
<tr><td>Conclusions regarding safety and effectiveness:</td><td>Based on the comparisons of intended use, and results of nonclinical and clinical testing, the ExSpiron™ is substantially equivalent in intended use, safety, and effectiveness to the nSpire Respirometer and to the breathing frequency monitor function of the Philips Intellivue Patient Monitors.</td></tr>
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 26 2012

Respiratory Motion, Incorporated
C/O Mr. Chas Burr
Chas Burr QR Services
11 Mystic Avenue
Winchester, Massachusetts 01890

Re: K120087
Trade/Device Name: ExSpiron™
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ, BZK
Dated: September 20, 2012
Received: September 21, 2012

Dear Mr. Burr:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K120087
Device Name: ExSpiron
Indications for Use:

ExSpiron 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 of age) patients.

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- Tidal volume,
- Respiratory rate, and
- Minute ventilation.

ExSpiron measurements are used as an adjunct to other clinical information sources.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120087