K130170

510(k) Summary

MAY 2 9 2013

510(k) Owner	Respiratory Motion, Inc.
Address	305 Second Avenue, Suite B Waltham, Massachusetts 02451
Phone	781-373-1636
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Contact person	Jenny Freeman, MD
Date 510(k) Summary prepared	January 13, 2013
Trade name	ExSpiron™ 1xi
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	ExSpiron Respiratory Monitor, cleared in 510(k) K120087.
Device Description	The ExSpiron 1xi system 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. • **Computer**: 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. 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™ 1xi Electrode PadSet:** An electrode assembly containing six electrodes to be placed on the torso. It delivers current and records impedance measurements. The electrode PadSet is also used to perform subsystem checks prior to patient measurements.
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 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.

<table>
<tr><td>Comparison of technological characteristics</td><td>
<table>
<tr><th>Characteristic</th><th>ExSpiron 1xi</th><th>ExSpiron</th><th>Comment</th></tr>
<tr><td>Intended Use</td><td>See above</td><td>Same</td><td>The Indications for Use are not changed in this Special 510(k).</td></tr>
<tr><td>Technology</td><td>Measurement is by thoracic bioimpedance.</td><td>Same</td><td>The fundamental technology is not changed</td></tr>
<tr><td>Volume Measurements</td><td>Tidal volume

Minute volume

Volume vs. time chart</td><td>Same</td><td>No change</td></tr>
<tr><td>Rate Measurements</td><td>Respiratory rate (breaths/min)</td><td>Same</td><td>No change</td></tr>
<tr><td>Safety</td><td>IEC 60601-1, second edition</td><td>Same</td><td>No change</td></tr>
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</td></tr>
<tr><td>Nonclinical performance testing:</td><td>Performance testing addressed specific modifications to the Monitor, Patient Cable, and Electrode PadSet as follows:
Software Verification & Validation
Safety Testing - IEC 60601-1 2nd Edition
Electromagnetic Compatibility - IEC 60601-1-2
ExSpiron 1Xi System Test Plan
Patient Cable Design Verification - Included testing to all the relevant sections of AAMI / ANSI EC53:1995/(R) 2008, ECG Cables and Leadwires
Electrodé PadSet Design Verification - Included testing to all the relevant section of AAMI / ANSI EC12:2000/(R)2010, Disposable ECG Electrodes & AAMI / ANSI EC53:1995/(R) 2008, ECG Cables and Leadwires
Electrode - Biocompatibilty – ANSI/AAMI/ISO 10993-1 (Skin, prolonged duration)
All performance testing conducted on modifications to the Monitor, Patient Cable, and Electrode Padset were completed with successful results. Performance testing raised no new safety or efficacy concerns and demonstrated substantial equivalence to the predicate device.</td></tr>
<tr><td>Clinical performance testing:</td><td>No clinical testing was performed for this 510(k). The measurement algorithm and software are unchanged from the predicate. Measurement performance statistics were determined by clinical trials reported in the predicate 510(k), K120087.</td></tr>
<tr><td>Conclusions regarding safety and effectiveness:</td><td>Based on the comparisons of intended use and on the results of testing, the ExSpiron 1xi is substantially equivalent in intended use, safety, and effectiveness to the ExSpiron respiratory monitor.</td></tr>
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 29, 2013

Jenny Freeman, M.D.
President
Respiratory Motion
305 Second Avenue, Suite B
WALTHAM, M.A. , 02451

Re: K130170
Trade/Device Name: ExSpiron™ 1xi
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: II
Product Code: BZK, BZQ
Dated: April 26, 2013
Received: April 29, 2013

Dear Ms. Freeman:

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 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. 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,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K130170
Device Name: ExSpiron 1xi
Indications for Use:

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ExSpiron 1xi 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 1xi measurements are used as an adjunct to other clinical information sources.

Lester W. Schultheis Jr
2013.05.29 10:50:39 -04'00'

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

510(k) Number: K130170

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