January 30, 2020

Linshom Management LLC
Ronen Feldman
President
2922 Excelsior Springs Court
Ellicott City, Maryland 21042

Re: K190734
Trade/Device Name: Linshom Respiratory Monitoring Device (LRMD)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: January 1, 2020
Received: January 2, 2020

Dear Ronen Feldman:

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)*
K190734

Device Name
Linshom Respiratory Monitoring Device (LRMD)

Indications for Use *(Describe)*
Linshom Respiratory Monitoring Device (LRMD) is indicated for use by healthcare professionals in healthcare facilities, such as procedural areas and recovery rooms, to monitor breathing in adult (at least 22 years of age) patients.

LRMD is a non-invasive system that graphically displays temperature changes against time and reports values of respiratory rate and seconds since last breath, along with a trend of tidal volume.

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

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 – K190734

(per 21 CFR 807.92)

Submitter Information

Name	Linshom Management LLC
Address	2922 Excelsior Springs Court Ellicott City, MD 21042
Phone Number	(410) 480-2700
Contact Person	Ronen Feldman President
Date Prepared	January 30, 2020

Device Information

Trade Name	Linshom Respiratory Monitoring Device (LRMD)
Common Name	Respiratory Monitor
Classification	Breathing frequency monitor 21 CFR 878.2375 (Product Code BZQ)

Predicate Device Information

Primary Predicate	ExSpiron, K120087
Reference Device	ReDe Mask, K161953

Device Description

The Linshom Respiratory Monitoring Device (LRMD) is a medical device designed to monitor a patient's respiratory rate, tidal volume trend and seconds since last breath within a healthcare setting. The LRMD is a thermistor based respiratory monitor which includes the Thermistor Sensor Assembly (TSA), Integrated Linshom Module (ILM) Core, the power supply and software.

Indications for Use

Linshom Respiratory Monitoring Device (LRMD) is indicated for use by healthcare professionals in healthcare facilities, such as procedural areas and recovery rooms, to monitor breathing in adult (at least 22 years of age) patients.

LRMD is a non-invasive system that graphically displays temperature changes against time and reports values of respiratory rate and seconds since last breath, along with a trend of tidal volume.

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

Technological Characteristics

As shown in Table 1, many technological similarities exist between the subject and predicate devices. The operating mechanism utilized in the LRMD is thermistor-based, similar to the cited reference predicate. Other technological characteristics of LRMD, including software, EMC and ES, and usability aspects, are similar to predicate devices.

Characteristic	**Subject Device** **LRMD**	**Predicate Device (K120087)** **ExSpiron**	**Reference Device (K161953)** **ReDe Mask**	**Comparison**
Trade Name	Linshom Respiratory Monitoring Device (LRMD)	ExSpiron	ReDe Mask	
Common Name	Respiratory Monitor	Respiratory Monitor	Breathing Monitor	
510(K) Number	K190734	K120087	K161953	
Regulation Classification (Product Code)	21 CFR 868.2375 (BZQ)	21 CFR 868.2375 (BZQ) AND 21 CFR 868.1850 (BZK)	21 CFR 879.2375 (PRK)	Same
Intended Use	Non-invasive monitoring of respiration and tidal volume trends for adults in healthcare settings	Non-invasive monitoring of respiration and tidal volume for adults in healthcare settings	Non-invasive monitoring of respiration for adults in healthcare settings	Same (ExSpiron)
Indications for Use	Linshom Respiratory Monitoring Device (LRMD) is indicated for use by healthcare professionals in healthcare facilities, such as procedural areas and recovery rooms, to monitor breathing in adult (at least 22 years of age) patients. LRMD is a non-invasive system that graphically displays temperature changes against time and reports values of respiratory rate and seconds since last breath, along with a trend of tidal volume. LRMD measurements are used as an adjunct to other clinical information sources.	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. 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.	The ReDe Mark is indicated for use by healthcare professionals in healthcare facility procedural areas and recovery rooms as an adjunct to monitor breathing in adult patients who are sedated for a diagnostic or therapeutic procedure. The ReDe Mask measures the time period between the current and previous exhalation and illuminates a colored light during the exhalation that reflects the interval of time between breaths. If the interval is less than 7.5 seconds, the green light illuminates during exhalation; if the interval is greater than 7.5 seconds but up to 20 seconds, the yellow light illuminates during exhalation; and if the interval between breaths is 20 seconds or longer, the red light flashes continuously. The ReDe Mask is only to be used when supplemental oxygen is provided by the facemask. The ReDe Mask is not a standalone device and is only to be used as an adjunct to pulse oximetry.	Equivalent (ExSpiron) Minor text differences to not suggest a new or difference intended use. Justification: minor differences reflect minor differences in devices but does not change the use, users, or conditions of use
Mechanism (General)	Thermistor	Thoracic Bioimpedence	Thermistor	Same (ReDe Mask)
Measurements	Respiratory Rate Seconds Since Last Breath Tidal Volume Trend	Respiratory Rate Tidal Volume Minute Volume	Seconds Since Last Breath	Equivalent (All) Justification: these parameters are all related to the breathing cycle

Characteristic	**Subject Device** **LRMD**	**Predicate Device (K120087)** **ExSpiron**	**Reference Device (K161953)** **ReDe Mask**	**Comparison**
Communication Method	GUI Interface	GUI Interface	Light Display (Red / Yellow / Green)	Same (ExSpiron)
ES / EMC Testing	IEC 60601-1 & 60601-1-2	IEC 60601-1 & 60601-1-2	IEC 60601-1 & 60601-1-2	Same
Material Biocompatibility	ISO 10993 ISO 18562	unknown	Tested (mask components)	Equivalent Justification: all devices address biocompatibility risks (albeit different mechanisms)
Mask Type	Face mask	ExSpiron 1Xi PadSets	Face mask	Equivalent (ReDe Mask) Justification: LRMD utilizes a legally marketed facemask while the ReDe Mask incorporates its own mask; regardless, both devices attach to the patient face via an oxygen mask
Mounting Design	Sensor attached to separate electronics box	Electrodes attached to separate electronics box	Face mask and electronics housing placed on patient's face	Equivalent (ExSpiron) Justification: these are similar concepts just have different electronics
Ambient Operating Temperature	65°F – 85°F (18.3°C – 29.4°C)	Unknown	16°C to 31°C	Equivalent (ReDe Mask) Justification: both devices demonstrate safe and effective performance at the extremes of its stated operating range
Working Range	Respiration: 5-60 BPM Tidal Volume: 120-1000mL	Respiration: 5-30 BPM Tidal Volume: unknown	Unknown	Equivalent (ExSpiron) Justification: both devices have performance testing that demonstrates safety and effectiveness against a gold standard (e.g., capnography) for the entire working range
Accuracy	Respiration: ± 1 BPM Tidal Volume Trend: 0.97 (r^2 correlation to ventilator)	Respiration: 2% Tidal Volume: 3.9%	Unknown	Equivalent (ExSpiron) Justification: although LRMD reports its accuracy across the working range (via correlation), performance data showed that accuracy is equivalent across working range for both respiration and tidal volume
Weight *(at point of measurement)*	~15g (Thermistor Sensor Assembly only)	unknown	40g	Within Range of Existing Products
Dimensions *(of unit as point of measurement)*	60mm H 254mm L 158mm W (ILM Core)	unknown	43.43mm H 30.48mm W 14.99mm D	Within Range of Existing Products
Performance Testing	Lifetime Test (24hr) Breathing Rate Test (Mechanical Lung) Movement Test 38 volunteer subjects (for respiratory rate) 12 endoscopy subjects (for respiratory rate) 40 volunteer subjects (for tidal volume) Human Factors Test Tidal Volume Trend Bench Test	20 subjects (for all 3 measures, compared against spirometer)	Lifetime Test (8hr) Human Factors (for overall use and for light interpretation) 38 volunteer subjects (for detection of exhalation and low respiratory rate compared to capnography) 50 volunteer subjects (for detection of exhalation and low respiratory rate compared to capnography and bioimpedance)	Demonstrates subject device is as safe and as effective as predicate device.

Performance Data

Bench and clinical performance data were collected to support a substantial equivalence determination. This testing included mechanical lung data, patient movement simulation, 24-hour testing, clinical comparison of respiratory rate to capnography, and clinical comparison of tidal volume trend to a ventilator. These data suggest the LRMD is as safe and as effective as the identified predicate devices.

Conclusions

The LRMD and predicate devices have the same intended use and similar indications, both serving as medical devices to monitor respiration and tidal volume trend. As described above, the minor technological differences between the LRMD and its predicates do not present any new or different issues of safety or effectiveness. Based upon analysis and valid scientific evidence the LRMD is substantially equivalent to its predicate devices.