September 11, 2024

Linshom Medical Inc.
William Stoll
VP, Quality & Regulatory
2922 Excelsior Springs Court
Ellicott City, Maryland 21042

Re: K240271
Trade/Device Name: Linshom Continuous Predictive Respiratory Monitoring System (CPRMS)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: March 26, 2024
Received: March 26, 2024

Dear William Stoll:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2024.09.11 15:50:34 -04'00'

For

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240271

Device Name
Linshom Continuous Predictive Respiratory Monitoring System (CPRMS)

Indications for Use *(Describe)*
Linshom Continuous Predictive Respiratory Monitor System (CPRMS) 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.

The CPRMS 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.

CPRMS 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Linshom
Every Breath Counts™

510(k) Summary
21 CFR 807.92

Submitter Information

Name	Linshom Medical, Inc.
Address	2922 Excelsior Springs Court Ellicott City, MD 21042
Phone Number	(716) 474-8572
Contact Person	William A. Stoll VP, Quality & Regulatory
Date Prepared	September 4, 2024

Subject Device Information

Trade Name	Linshom - Continuous Predictive Respiratory Monitoring System (CPRMS)
Common Name	Respiratory Monitor
Classification	Breathing frequency monitor 21 CFR 878.2375 (Product Code BZQ)
510(k) Number	K240271

Predicate Device Information

Device Name	Linshom Respiratory Monitoring Device (LRMD)
Classification	Breathing frequency monitor 21 CFR 878.2375 (Product Code BZQ)
510(k) Number	K190734

Device Description Summary

The Linshom CPRMS (Continuous Predictive Respiratory Monitoring System) is portable, reliable and an inexpensive system for precise detection of spontaneous respiration. It is non-invasive and is not corrupted by motion artifacts. The system autonomously adapts to the local thermal environment to deliver a usable signal without complicated hardware and firmware processing.

Indications for Use

Linshom Continuous Predictive Respiratory Monitor System (CPRMS) 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.

The CPRMS 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.

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

Technological Comparison to Predicate Device

Table 1: Comparison of Technological Characteristics

Characteristic	**Subject Device Linshom CPRMS w/ 2-piece sensor**	**Predicate Device (K190734) LRMD**	**Comparison Outcome**
Trade Name	Continuous Predictive Respiratory Monitoring System (CPRMS)	Linshom Respiratory Monitoring Device (LRMD)	Same
Common Name	Respiratory Monitor	Respiratory Monitor	Same
510(K) Number	K240271	K190734	
Regulation Classification (Product Code)	21 CFR 868.2375 (BZQ)	21 CFR 868.2375 (BZQ)	Same
Indications for Use	Linshom Respiratory Monitoring Device (CPRMS) 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 22 years of age) patients. CPRMS is a non-invasive system that graphically displays temperature changes against time and reports values of respiratory rates and seconds since last breath, along with a trend of tidal volume. CPRMS measurements are used as an adjunct to other clinical information sources.	Linshom Respiratory Monitoring Device (LRMD) 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 22 years of age) patients. LRMD is a non-invasive system that graphically displays temperature changes against time and reports values of respiratory rates and seconds since last breath, along with a trend of tidal volume. LRMD measurements are used as an adjunct to other clinical information sources.	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 trends for adults in healthcare settings.	Same
Mechanism (General)	Thermistor	Thermistor	Same

Characteristic	Subject Device Linshom CPRMS w/ 2-piece sensor	Predicate Device (K190734) LRMD	Comparison Outcome
Assembly (Specifications)	2 pieces	1 piece	Same Function – Assembly has been Verified & Validated
Connection (Specifications)	Compression	Epoxied	Same Function – Assembly has been Verified & Validated
Measurements	Respiratory Rate Seconds Since Last Breath Tidal Volume Trend	Respiratory Rate Seconds Since Last Breath Tidal Volume Trend	Same
Communication Method	GUI Interface	GUI Interface	Same
Software / Firmware	Proprietary Algorithm	Proprietary Algorithm	Same
Mask Type	Face mask	Face mask	Same
Mounting Design	Sensor attached to separate electronics box	Sensor attached to separate electronics box	Same
Ambient Operating Temperature	65°F – 85°F (18.3°C – 29.4°C)	65°F – 85°F (18.3°C – 29.4°C)	Same
Working Range	Respiration: 5-60 BPM Tidal Volume Trend	Respiration: 5-60 BPM Tidal Volume Trend:	Same
Accuracy	Respiration: ± 1 BPM Tidal Volume TREND: ~0.97 (r2 correlation).	Respiration: ± 1 BPM Tidal Volume Trend: 0.97 (r2 correlation to ventilator)	Same. The structural differences between the subject device (CPRMS) and the predicate device (LRMD), such as the two-piece assembly and compression connection, have been validated and shown not to affect the device's safety or effectiveness.
Weight *(at point of measurement)*	~15g (Thermistor Sensor Assembly only)	~15g (Thermistor Sensor Assembly only)	Same

Characteristic	Subject Device Linshom CPRMS w/ 2-piece sensor	Predicate Device (K190734) LRMD	Comparison Outcome
Dimensions *(of unit as point of measurement)*	60mm H 254mm L 158mm W (ILM Core)	60mm H 254mm L 158mm W (ILM Core)	Same

As described above in Table 1 the technological differences between the CPRMS and LRMD devices do not raise different questions of safety or effectiveness. Performance testing further confirms that these differences do not affect safety and/or efficacy.

Non-Clinical and/or Clinical Tests Summary

The subject device [K240271] underwent testing across the full range of physiological parameters, including respiratory rates from 0-60 breaths per minute (BPM). These tests demonstrated that the subject device meets performance expectations and supports its substantial equivalence to the predicate device. Statistical analysis, including correlation methods, showed strong alignment with reference data, indicating that the device functions accurately and reliably within its intended use parameters.

The following non-clinical testing was performed to support the substantial equivalence of the subject device:

- Lifetime Test (24hr)
- Movement Test
- Human Factors Test
- Sensor Integrity Testing
- Respiration Rate Test: 5-60 BPM
- Tidal Volume Trend Test

Testing was also performed to demonstrate substantial equivalence through conformance to the following standards/guidance documents:

- Biocompatibility
    - ISO 18562-1
    - ISO 10993-1
    - Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” – Guidance for Industry and Food and Drug Administration Staff, September 2023
- Electrical, Mechanical and Thermal Safety
    - IEC 60601-1
- Electromagnetic Compatibility
    - IEC 60601-1-2
    - Electromagnetic Compatibility (EMC) of Medical Devices – Guidance for Industry and Food and Drug Administration Staff, June 2022

- Human Factors
    - Applying Human Factors and Usability Engineering to Medical Devices – Guidance for Industry and Food and Drug Administration Staff, February 2016
- Software
    - Content of Premarket Submissions for Device Software Functions – Guidance for Industry and Food and Drug Administration Staff, June 2023

Conclusions

This nonclinical testing demonstrates substantial equivalence of the subject device CPRMS being as safe, as effective, and performing as well as the LRMD predicate device.