September 26, 2025

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

Re: K250093
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: August 22, 2025
Received: August 22, 2025

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: 2025.09.26 14:00:08 -04'00'

For

Rachana Visaria
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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)*
K250093

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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510(k) Summary

(per 21 CFR 807.92)

K250093

Submitter Information

Name	Linshom Medical, Inc.
Address	2922 Excelsior Springs Court Ellicott City, MD 21042
Phone Number	(410) 480-2700
Contact Person	William A. Stoll VP, Quality & Regulatory
Date Prepared	September 26, 2025

Device Information

Trade Name	Linshom Continuous Predictive Respiratory Monitoring System (CPRMS)
Common Name	Respiratory Monitor
Classification	Breathing frequency monitor 21 CFR 868.2375 (Product Code BZQ)

Predicate Device Information

Device Name	Linshom Continuous Predictive Respiratory Monitoring System (CPRMS)
Classification	Breathing frequency monitor 21 CFR 868.2375 (Product Code BZQ)
510(k) Number	K240271

Device Description

The Linshom CPRMS (Continuous Predictive Respiratory Monitoring System) is a portable and reliable system for detection of spontaneous respiration. It's 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 Monitoring 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.

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.

Technological Characteristics – Comparison

Table 1: Comparison of Technological Characteristics

Characteristic	**Subject Device Linshom CPRMS (K250093)**	**Predicate Device Linshom CPRMS (K240271)**	**Comparison Outcome**
Trade Name	Continuous Predictive Respiratory Monitoring System (CPRMS)	Continuous Predictive Respiratory Monitoring System (CPRMS)	Same
Common Name	Respiratory Monitor	Respiratory Monitor	Same
510(K) Number	K250093	K240271	
Regulation Classification (Product Code)	21 CFR 868.2375 (BZQ)	21 CFR 868.2375 (BZQ)	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

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Characteristic	Subject Device Linshom CPRMS (K250093)	Predicate Device Linshom CPRMS (K240271)	Comparison Outcome
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 (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.	Same
Mechanism (General)	Thermistor	Thermistor	Same
Assembly (Specifications)	2 pieces	2 pieces	Same
Connection (Specifications)	Compression	Compression	Same
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
Safety / EMC Testing	IEC 60601-1 & 60601-1-2 2-piece sensor and ILM	IEC 60601-1 & 60601-1-2 2-piece sensor and ILM	Same
Material Biocompatibility	ISO 18562-2:2017 ISO 18562-3:2017 ISO 10993-5:2009	ISO 18562-2:2017 ISO 18562-3:2017 ISO 10993-5:2009	Same
Mask Type	Face mask (oxygen) - Adult open	Face mask (oxygen) - Adult standard	Same Function

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Characteristic	Subject Device Linshom CPRMS (K250093)	Predicate Device Linshom CPRMS (K240271)	Comparison Outcome
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)	Same
Weight *(at point of measurement)*	~15g (Thermistor Sensor Assembly only)	~15g (Thermistor Sensor Assembly only)	Same
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 open oxygen mask and CPRMS standard oxygen mask devices do not raise any/new 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

Clinical bench testing was conducted to evaluate the performance of the subject device, the Open Oxygen Mask (K250093), compared to the predicate Standard Oxygen Mask (K240271), using the same FDA-cleared Linshom two-piece sensor and electronics. Human volunteer testing was performed across the full physiologic range of respiratory rates (10–60 breaths per minute) under metronome guidance. A total of 12 volunteers were tested with the open mask and 6 volunteers with the standard mask, with 5 volunteers participating in both arms to allow direct within-subject comparison. Data collection included raw respiratory signals and derived respiratory rate values, which were statistically analyzed using Pearson correlation and Bland-Altman methods. Results demonstrated very high correlation ($r \geq 0.98$ across all cases) between the measured respiratory rates and the metronome reference, with minimal bias and narrow limits of agreement. Overlays of raw respiratory signals confirmed that both mask configurations produced consistent waveform patterns and equivalent respiratory rate outputs. Together, these bench performance tests confirm that the change in mask design does not adversely affect sensor function and support a determination of substantial equivalence.

K250093

Biocompatibility

The biocompatibility evaluation for the Linshom CPRMS [K250093] was conducted in accordance with ISO 10993-1:2018, ISO 18562-1:2024, and FDA's 2023 Biocompatibility Guidance document and was based on materials-based rationale in conjunction with biological testing.

Conclusions

Clinical and non-clinical testing demonstrates substantial equivalence of the subject device CPRMS being as safe, as effective, and performing as well as the CPRMS predicate device.