



August 7, 2025

Sentec AG
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
St Petersburg, Florida 33704

Re: K243765

Trade/Device Name: LuMon™ System
Regulation Number: 21 CFR 868.1505
Regulation Name: Ventilatory Electrical Impedance Tomograph
Regulatory Class: Class II
Product Code: QEB, BZQ
Dated: December 6, 2024
Received: December 6, 2024

Dear Paul Dryden:

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,

John S. Bender -S
2025.08.07 13:02:53 -04'00'

for Ethan Nyberg, Ph.D.
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

Indications for Use

510(k) Number (if known)
K243765

Device Name
LuMon™ System

Indications for Use (Describe)

The LuMon™ System is a noninvasive, non-radiation device that provides information on regional impedance variation within a cross-section of a patient's thorax. Graphical and numerical information is presented to the user as an adjunctive tool to other clinical information to support the user to assess a patient's respiratory condition.

The LuMon™ System is indicated for neonatal and infant patients with chest circumferences between 16.5 - 50 cm and adolescent through adult patients with chest circumferences between 76 - 128 cm who are breathing spontaneously or require mechanical ventilation in professional healthcare facilities.

Impedance-based respiratory rate monitoring is indicated for adults 22 years and older whose chest circumference is above 76 cm only.

The LuMon™ System also displays selected physiological and respiratory parameters from supported bedside devices.

The LuMon™ System does not measure regional ventilation of the lungs.

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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Date Prepared: 6-Aug-25

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Sponsor Contact: Caroline Möller, Dr.,
Head of Regulatory Affairs and Quality Assurance

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: LuMon™ System
Classification Name: Ventilatory electrical impedance tomograph
Product Code: QEB

Predicate Device: Timpel Enlight 2100
Classification Name: Ventilatory electrical impedance tomograph
Product Code: QEB

Reference Device: Drager Infinity® Acute Care System™ (IACS) Monitoring
Solution with Infinity® M540 Patient Monitor
Common/Usual Name: Physiological Patient Monitor
Classification Name: Monitor, Physiological, Patient (with arrhythmia detection or
Alarms)
Product Code: BZQ

Device Description

The LuMon™ System is a compact and lightweight Electrical Impedance Tomography (EIT) system that provides noninvasive monitoring of variations of regional air content/volume within a cross-section of the patient's thorax and patient respiration. It displays the results as real-time EIT images, waveforms, and derived parameters.

The system consists of a controller display unit, signal acquisition connector cable, and patient-applied conductive textile electrode belts. The system can connect to external bedside devices such as ventilators and monitoring devices to display contextual information for interpretation of EIT measurements.

Principle of Operation

The LuMon™ System is based on the principles of Electrical Impedance Tomography (EIT), where weak alternating currents are applied and travel along the paths of least resistance through an object, and the resulting electrical potentials at the object's surface are continuously measured by an array of electrodes placed on the object. Typically, electrode arrangements are designed to sequentially pick up signals coming from different directions. In this way, the electrical "point of view" is

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constantly changing, and images reflecting regional impedance within the object and variations thereof can be created with frame rates of 50 Hz.

Intended Use

The LuMon™ System is a non-invasive, non-radiation device that provides information on regional impedance variation within a cross-section of a patient's thorax as an adjunctive tool to other clinical information to support the user in assessing a patient's respiratory condition. The LuMon™ System also displays selected physiological and respiratory parameters from supported bedside devices.

Indications for Use

The LuMon™ System is a non-invasive, non-radiation device that provides information on regional impedance variation within a cross-section of a patient's thorax. Graphical and numerical information is presented to the user as an adjunctive tool to other clinical information to support the user to assess a patient's respiratory condition.

The LuMon™ System is indicated for neonatal and infant patients with chest circumferences between 16.5 - 50 cm and adolescent through adult patients with chest circumferences between 76 - 128 cm who are breathing spontaneously or require mechanical ventilation in professional healthcare facilities.

Impedance-based respiratory rate monitoring is indicated for adults 22 years and older whose chest circumference is above 76 cm only.

The LuMon™ System also displays selected physiological and respiratory parameters from supported bedside devices.

The LuMon™ System does not measure regional ventilation of the lungs.

Patient Population

Neonatal and infant patients with chest circumferences between 16.5 - 50 cm and adolescent through adult patients with chest circumference between 76 - 128 cm who are breathing spontaneously or requiring mechanical ventilation in professional healthcare facilities.

Impedance-based respiratory rate monitoring is indicated for adults 22 years and older whose chest circumference is above 76 cm only.

Environments of use

Professional healthcare facilities.

Substantial Equivalence Discussion

Indications – Both devices have similar intended uses and indications. The subject device extends to patients with smaller chest circumferences. The subject device measures and displays a few additional parameters derived from the same information presented on both devices.

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Technology and construction – The operating principle and EIT technology are the same for both subject and predicate devices. The subject and reference device share the use of low-current bioimpedance measurement technology, with EIT benefiting from a larger number of electrodes to improve respiratory rate measurements. The predicate device uses integrated spirometry modules for respiratory rate determination but displays and uses the information similarly to the subject device.

Environment of Use – The environment of use for both devices is professional healthcare environments such as the hospital.

Patient Population – The subject device is indicated for both spontaneously breathing patients and those on mechanical ventilation, whereas the predicate is only indicated for mechanically ventilated patients. The submission presents extensive validation in patients without and with various forms of respiratory support, under conditions such as rapid and shallow breathing, irregular breathing, and coughing, and in different patient orientations (supine, prone, lateral) to support the extension to this broader patient group.

The subject device is intended for pre-term neonatal, infant, and adolescent through adult patients matching the available belt circumferences, whereas the predicate is indicated only for pediatric through adult patients. This submission provides bench, pre-clinical, and clinical validation data for regional impedance measurements across the full range of available belt sizes. Respiratory rate indications are available for the adults 22 years and older with a chest circumference greater than 76 cm.

The testing demonstrates that this expanded patient population can use the subject device as intended.

For Drager Infinity® Acute Care System™ (IACS) Monitoring Solution with Infinity® M540 Patient Monitor, as a reference device

Indications – The LuMon™ System provides a subset of the indications, namely for measuring respiration rate via thoracic bioimpedance.

Technology and construction – Both devices present respiratory rate information derived from the impedance plethysmogram. The subject device derives the plethysmogram from 32 electrodes for improved accuracy.

Environment of Use – There is no difference in the environment of use.

Patient Population – The intended patient population for the LuMon™ System, specifically for breathing frequency, is adults 22 years and older with a chest circumference above 76 cm. The reference device also includes neonates.

Non-Clinical Testing Summary

Bench testing – We have performed the following performance tests. All specified requirements were met.

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- FDA EIT Special Controls Analysis
- EC53 Analysis (limited test scope)
- FDA EIT special controls with predicate comparison and measurement performance
- EIT image performance testing (with failing electrodes)
- EIT parameter performance (impedance distribution changes and volume related impedance changes)
- Accessories Use Life
- Reprocessing (Durability)
- Respiration Rate Bench Test
- Model mismatch validation
- Failing electrode compensation validation
- Patient position measurement validation
- Repeatability of belt placement analysis

Electrical safety and electromagnetic compatibility (EMC) - Electrical safety and EMC testing were conducted on the LuMon™ System. The system complies with IEC 60601-1 and IEC 60601-1-2.

Software Verification and Validation Testing - Software verification and validation testing were conducted and documented as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

Biocompatibility – The proposed device and the predicate have the same category of patient contact. Testing for Surface Contact was performed per ISO 10993-1, and the results supported safe use for the intended purpose and duration of use.

Human factors – Usability validation was performed per IEC 62366-1, AAMI HE75, and FDA’s Guidance “Applying Human Factors and Usability Engineering to Medical Devices”.

Pre-Clinical Testing Summary

Pre-clinical testing was conducted to evaluate performance in neonatal and infant patients where suitable clinical validation data was not feasible due to ethical concerns. The table below presents an overview of the pre-clinical validation studies.

Table 1. Summary of pre-clinical validation studies.

Characteristic(s)	Subjects	Comparators
Regional impedance distribution	Rabbit and piglet models with circumferences spanning 19 to 50 cm representing the neonatal and infant ICU patients	Differential CT changes in aeration with different PEEP levels for both healthy and surfactant-depleted, injured lungs. Regional CT comparison for both one- and two-sided intubation. Established physiological changes due

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		to hyper- and hypo-ventilation, changes in PEEP, and tidal volume.
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The studies confirmed the ability of the LuMon™ EIT monitor to evaluate regional aeration and ventilation distribution changes. Various clinical conditions and the full range of ventilation settings (PEEP and driving pressure) were assessed. In each case, the corresponding measurements for aeration/recruitment (as assessed via EELI) and ventilation (as assessed with EIT tidal variation images and global TVi) matched the expected changes from established physiology.

The agreement between EIT and CT regional aeration distribution was assessed. Comparisons were performed for the right and ventral lung regions of interest. The R-squared correlation was excellent at 0.98 between right EIT and CT values and 0.97 between ventral EIT and CT values across all subjects. Using Bland-Altman analysis, bias and precision were well within the pre-defined tolerance for right and ventral measurements.

These pre-clinical validation studies confirmed the ability of the LuMon™ EIT monitor to evaluate regional aeration and ventilation distribution changes in a pre-clinical model representing the neonatal/infant patient population for the complete range of belt sizes spanning from 19 cm equivalent to very low birth weight pre-term neonates to 47 cm thorax circumference for infants.

Clinical testing

Clinical testing was performed to support safety and effectiveness for the proposed population, environments of use, and displayed parameters. This includes the following for both healthy volunteers and patients.

- Global volume measurement
- Regional impedance distribution
- Respiration Rate

Table 2. Summary of clinical validation studies.

Characteristic(s)	Subjects	Comparators
Global volume changes	Healthy Adult Volunteers Adult ICU patients on mechanical ventilation with stepped PEEP and tidal volumes	Body plethysmograph traces Ventilator flow-sensed volumes
Regional impedance distribution	Healthy Adult Volunteers in supine, prone, left and right lateral positions	Timpel 2100 predicate comparison
Respiration rate (spontaneous breathing at different suggested frequencies)	Healthy Adult Volunteers (spontaneous breathing at different suggested rates with various irregular, deep, shallow, rapid, and coughing conditions)	Clinician-scored EtCO ₂ capnogram

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	Adult spontaneously breathing and mechanically ventilated ICU patients	
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Collectively, these multiple lines of evidence validated the ability of LuMon™ System to accurately reflect spatial, relative amplitude, and temporal changes in ventilation as well as respiratory rate to the corresponding reference standards or predicate device (regional distribution).

Substantial Equivalence Conclusion

The LuMon™ System has the same intended use as the predicate device, and the differences in technological characteristics do not raise different questions of safety and effectiveness. Any technological differences have been addressed with appropriate bench, performance, clinical, and safety testing to show that the LuMon™ System is at least as safe and effective as the predicate device. Therefore, these devices are substantially equivalent.

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Comparison of Technological Characteristics and Performance with the Predicate and Reference

Table 3 – Comparison – Subject vs. Predicate Device – EIT Data

Attributes	Subject Device LuMon™ System	Primary Predicate Device Timpel Enlight 2100	Comparison
510(k)		K222987	
Product Code(s)	QEB; BZQ	QEB; BZK	LuMon™ monitor has same product codes for relevant predicate device features
Regulation Number(s)	21 CFR Part 868.1505 21 CFR Part 868.2375	21 CFR Part 868.1505 21 CFR Part 868.1850	
Prescription Device	Yes	Yes	Same
Intended Patient Population	Adolescents through adults, infants, and neonates for electrical impedance tomography (EIT) measurement Adolescents through adults for respiratory rate (breathing frequency)	Adults and pediatrics who are Mechanically ventilated patients, for electrical impedance tomography (EIT) measurement and respiratory rate.	LuMon™ System is proposed to include neonates and infants for EIT measurements except for respiratory rate.
Indications for Use	The LuMon™ System is a noninvasive, non-radiation device that provides information on regional impedance variation within a cross-section of a patient's thorax. Graphical and numerical information is presented to the user as an adjunctive tool to other clinical information to support the user to assess a patient's respiratory condition. The LuMon System is indicated for neonatal and infant patients with chest circumferences between 16.5 - 50 cm and adolescent through adult patients with chest circumferences	ENLIGHT 2100 is a non-invasive, radiation free medical device that provides information from impedance variation from a cross-section of a patient's thorax. This information is presented to the clinician user as an adjunctive tool to support the user's assessment of variations in regional air content within a cross section of a patient's thorax. ENLIGHT 2100 also provides respiratory parameters based on spirometric monitoring. It is intended for mechanically	Similar to the predicate for EIT functionality. LuMon is proposed for use additionally with non-mechanically ventilated patients.

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	<p>between 76 - 128 cm who are breathing spontaneously or require mechanical ventilation in professional healthcare facilities.</p> <p>Impedance-based respiratory rate monitoring is indicated for adults 22 years and older whose chest circumference is above 76 cm only.</p> <p>The LuMon™ System also displays selected physiological and respiratory parameters from supported bedside devices.</p> <p>The LuMon™ System does not measure regional ventilation of the lungs.</p>	<p>ventilated adult and pediatric patients in a hospital setting, whose thorax perimeter is within the range of 37.5 – 134 cm.</p> <p>ENLIGHT 2100 does not measure regional ventilation of the lungs.</p>	
Environment of Use	Professional healthcare settings	Hospital setting	Similar – healthcare and professional use environments
Duration of Use	Up to 30 days, with Belt change each 72 hours.	Up to 30 days, with Addere change each 48 hours.	Similar
Contraindications	<ul style="list-style-type: none"> The patient has active implants (pacemaker or defibrillator). The patient has an external pacemaker or defibrillator. 	<ul style="list-style-type: none"> Must not be used in patients with implantable electronic devices. Must not be used on pregnant or lactating patients, once the safety and efficiency for such cases have not been verified. 	Similar for LuMon™ and predicate device.
Principles of operation	Electrical Impedance Tomography based on voltage measures to estimate local impedance variation within a cross section of a patient's thorax.	Electrical Impedance Tomography based on voltage measures to estimate local impedance variation within a cross section of a patient's thorax.	Same
Non-sterile	There are no sterile components or accessories.	There are no sterile components or accessories.	Same
Features			

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Shape	Monitor-like device, transportable	Monitor-like device, transportable	Equivalent
Monitor dimensions	Height: 30.8 cm Width: 21.8 cm Depth: 10.1 cm Weight: <4 kg	For system on cart: Height: 55 cm Width: 143 cm Depth: 46 cm Weight: 41.5 kg	Different – Predicate device is larger and heavier as it comes on a cart.
Patient-applied Accessory Application Site(s)/sizes	LuMon™ Belts and LuMon™ Contact Gel, applied on the circumference of the patient's thorax on intact skin – size ranges from 16.5 – 50 and 76 – 128 cm for chest circumference. The electrode belt is applied to the patient between the 4 th and 5 th intercostal spaces.	Thorax perimeter is within the range of 37.5 - 134 cm. The electrode belt is applied to the patient between the 4 th and 5 th intercostal spaces.	Smaller belt sizes are available for neonatal and infant populations compared to the predicate. Same application site.
Biocompatibility	Surface Contact Intact Skin Prolonged duration (>24 hours, <30 days)	Surface Contact Intact Skin Prolonged duration (>24 hours, <30 days)	Equivalent
Integrated Patient Position (Orientation) Sensor	Yes, continuous and automatic measurement and display. Enables accounting for the effects of gravity and patient orientation in displayed images and indices (integrated in the belt).	Not available. User must manually specify patient position through the GUI.	Different – measurement versus manual input in predicate. LuMon™ System position sensor supports the automatic recording and display of patient orientation and calculation of gravity-influenced indices
Connectivity	Interoperability to Sentec transcutaneous monitor for display (only) of selected transcutaneous measurements. Interoperability with specific ventilators for display (only) of selected ventilator measurement values. No alarms or control functionality supported.	No connectivity	Subject device provides one-way connectivity options for display (only) of selected values from specific third-party devices. Selected ventilator parameters are equivalent those presented by predicate from spirometry and pressure/flow sensors.

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System Parameters and Images			
End-expiratory lung impedance (EELI)	Displayed as Plethysmogram impedance waveform and trend the minima. Arbitrary units. Uncertainty of +/- 10% of reading.	Displayed as Plethysmogram impedance waveform but do not trend the minima values. It is dimensionless.	Equivalent as both show the plethysmogram. The predicate device only trends the full impedance plethysmogram whereas the subject device also trends the minima.
Positive End Expiratory Pressure (PEEP)	Displayed measurement from connected ventilator (when available)	Range: 1.0 – 50.0 cmH2O Accuracy: Max Error is less or equal to 1.0 cmH2O, Max Relative Error is less or equal to 2.47%.	Similar. Range, accuracy, and error depends on connected ventilator for subject device.
Peak Inspiratory Pressure	Displayed measurement from connected ventilator (when available)	Range: 1.0 – 120.0 cmH2O Accuracy: Max Error is less or equal to 0.44 cmH2O	Similar. Range, accuracy, and error depends on connected ventilator for subject device.
Resistance	Not available	Range: 5 – 40 cmH2O/L/s Accuracy: Bias:0 cmH2O/L/s, Std Dev: 3 cmH2O/L/s	Not displayed for subject device.
Compliance	Displayed measurement from connected ventilator (when available)	Range: 3 – 80 ml/cmH2O Accuracy: Bias: -1 mL/cmH2O, Std. Dev: 5 mL/cmH2O	Similar. Range, accuracy, and error depends on connected ventilator.
Plateau Pressure	Displayed measurement from connected ventilator (when available)	Range: 10.0 – 90.0 cmH2O Accuracy: Bias: 0.1 cmH2O, Std Dev: 1.1 cmH2O	Similar Range, accuracy, and error depends on connected ventilator for subject device.
Dynamic real-time EIT images	Yes – Dynamic Image	Yes - Dynamic Image	Same
Tidal Variation Image and value	Regional distribution of impedance changes between identified global plethysmogram maxima and minima. Numeric value also computed as the summed global value (TVi).	Distribution Map (image) and global Tidal Variation Z (value)	Equivalent

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Tidal Distribution Image	A Tidal Distribution Image is a normalized version of the Tidal Variation Image obtained for every Analysis Interval.	N/A	Normalized version of (equivalent) Tidal Variation Image for consistent scaling independent of global amplitude.
Differential Images	Available in trends screens to evaluate changes in regional impedance information between two time points for the following measurements: EELI, Tidal Variation, Tidal Distribution.	Available in trends screen for Distribution Map (Distribution Change Map).	Equivalent; subject device extends to include regional EELI changes.
Centroid of Thorax Impedance Changes	Center of Variation (CoV) Uncertainty of +/- 3% of p.p.	N/A	LuMon™ System provides CoV w/respect to gravity vector coordinates. Calculated from the Tidal Variation Image. Alternative representation of ROI distribution ratios.
Region of Interest Distribution Ratios	Left, Right, Ventral, Dorsal, Layers (ventral, middle, dorsal), Quadrants.	Left, Right, Anterior, Posterior	Equivalent
Performance characteristics – Non-clinical / Bench Test			
Distribution Ratios	Range: 0 – 100% Uncertainty of +/- 10 p.p. for Anterior, Posterior, Left and Right distribution ratio.	Range: 0 – 100% Uncertainty of +/- 10 p.p. for Anterior, Posterior, Left and Right distribution ratio.	Equivalent
Tidal Variation Z (TVz)	Arbitrary impedance units with no defined range. Uncertainty of +/- 10% of reading.	Range: 20% to 500% Uncertainty of +/- 10% of reading.	Equivalent; the predicate scales and limits range; same uncertainty in readings.
Tidal Variation Rate	Adult: 5 – 60 bpm ±2.0 bpm	Adult: 5 to 50 bpm, Pediatric: 10 to 140 bpm ±2.0 bpm if ≤ 60 bpm, ±5.0 bpm if > 60 bpm	Range is similar, accuracy is equivalent

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Minute Variation Index (MVi)	Product of the Respiration Rate R _{Ri} and the Tidal Variation TV _i over the Analysis Interval. Arbitrary impedance units with no defined range. Uncertainty of +/- 10% of reading.	User can manually compute the value from the numeric values and trends as the product of the Tidal Variation Rate (TVR) and Tidal Impedance Variation (TIV).	Similar
Signal to Noise Ratio (SNR) [db]	Min – Max (Mean): 45.0 – 84.9 (62.2)	50 - 95	A reported value only but similar
Voltage Accuracy [%]	Min – Max (Mean): 91.1 - 100.0 (99.1)	80 - 100	
Drift	Allan Variance converges to zero (below 100pV ²)	Allan Variance converges to zero (below 100pV ²)	
Reciprocity Accuracy [%]	Min – Max (Mean): 90.33 - 100.0 (99.1)	95 - 100	
Amplitude response [%]	Min – Max (Mean): 92 - 111 (101)	90 - 104	Similar
Position error [%]	Min – Max (Mean): 0.6 - 11 (4.98)	< 4% of the radius	
Ringing	Min – Max (Mean): 0.3 – 0.5 (0.419)	< 0.6	
Resolution	Min – Max (Mean): 0.28 - 0.37 (0.324)	< 0.42	
Percentage error of Plethysmogram	below 3.7%	below 5%	Similar

Table 4 – Comparison – Subject vs. Reference Device – Respiratory Rate Data

Attributes	Subject Device LuMon™ System	Reference Device Draeger Infinity® Acute Care System™ (IACS) Monitoring Solution with Infinity® M540 Patient Monitor	Comparison
510(k)		K113798	
Product Code(s)	QEB; BZQ	MHX, with subsequent codes: BZQ CCK DQA DRT	Reference has additional codes due to other functionality.

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		DSK DXN FLL FLS MLD MSX	Subject shares BZQ for monitoring of breathing frequency. The reference device is added for respiration rate via thoracic bioimpedance only.
Regulation Number(s)	21 CFR Part 868.1505 21 CFR Part 868.2375	21 CFR Part 870.1025 21 CFR Part 868.2375 relevant for breathing frequency monitor Others which are not pertinent to this submission	LuMon™ System does not claim apnea monitoring nor other monitoring features of the reference device with the exception of breathing frequency monitor.
Prescription Device	Yes	Yes	Equivalent
Intended Patient Population	Adolescents through adults, infants, and neonates for electrical impedance tomography (EIT) measurement Adults 22 years and older for respiratory rate (breathing frequency)	Adults through Neonates for all parameters including respiratory rate (breathing frequency)	LuMon™ System is proposed to include neonates for EIT measurements except for respiratory rate.
Indications for Use	The LuMon™ System is a noninvasive, non-radiation device that provides information on regional impedance variation within a cross-section of a patient's thorax. Graphical and numerical information is presented to the user as an adjunctive tool to other clinical information to support the user to assess a patient's respiratory condition. The LuMon System is indicated for neonatal and infant patients with chest circumferences between 16.5 - 50 cm and adolescent through adult patients with chest circumferences between 76 - 128 cm who are	The Infinity® Acute Care System™ (IACS) Monitoring Solution: The IACS is intended for multi-parameter, physiologic patient monitoring, of adult, pediatric, and neonatal patients in environments where patient care is provided by trained healthcare professionals. The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and displays. The transfer of this data is accomplished by the Infinity network. Intended Use: Infinity M540 Patient Monitor	LuMon™ uses similar technology for respiratory rate as the Reference.

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	<p>breathing spontaneously or require mechanical ventilation in professional healthcare facilities.</p> <p>Impedance-based respiratory rate monitoring is indicated for adults 22 years and older whose chest circumference is above 76 cm only.</p> <p>The LuMon™ System also displays selected physiological and respiratory parameters from supported bedside devices.</p> <p>The LuMon™ System does not measure regional ventilation of the lungs.</p>	<p>The Infinity M540 is intended for the monitoring of multi-parameter physiological patient information obtained from connected hardware in environments where patient care is provided by trained healthcare professionals. The M540 is intended to monitor one patient at a time,</p> <p>Indications for Use</p> <p>The M540 monitors the following parameters:</p> <ul style="list-style-type: none"> - heart rate - Arrhythmia (adult and pediatric only) - 12-lead analysis - ST segment analysis including TruST® (adult and pediatric only) - 12-lead ST segment analysis (adult and pediatric only) - Apnea - Respiration rate - Invasive pressure - Non-invasive pressure - Temperature - Cardiac output - Arterial oxygen saturation - Pulse rate (SpO2) - Mainstream (etCO2) 	
<p>Environment of Use</p>	<p>Professional healthcare settings</p>	<p>Environments where patient care is provided by trained healthcare professionals</p>	<p>Equivalent</p>

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Contraindications	<ul style="list-style-type: none"> The patient has active implants (pacemaker or defibrillator). The patient has an external pacemaker or defibrillator. 	No contraindications mentioned.	Reference lists no contraindications.
Principle of operation (for respiratory rate measurement)	<p>Respiratory Rate derived from the impedance Plethysmogram (waveform)</p> <p>Quantified in breaths per minute (bpm).</p>	<p>For respiration monitoring: A harmless high frequency current is passed between two ECG electrodes on the patient's chest. Electrical resistance (impedance) between the electrodes varies with the expansion and contraction of the chest during inspiration and expiration. The M540 displays a respiration waveform and respiratory rate value from these impedance changes.</p> <p>The M540 can use the respiration signal for central apnea monitoring.</p>	<p>Equivalent</p> <p>Subject device does not claim use for apnea monitoring.</p>
Features			
Patient-applied Accessories	<p>LuMon™ Belts – Single-use, non-adhesive, for measurement of impedance variation across a cross-section of a patient's thorax</p> <p>LuMon™ Contact Gel</p>	Conventional ECG electrodes are applied for monitoring of ECG and simultaneous monitoring of respiration rate via thoracic bioimpedance	Equivalent – electrode application to chest wall through an electrically conductive medium.
Connectivity	<p>Interoperability to Sentec transcutaneous monitor for display (only) of selected transcutaneous measurements.</p> <p>Interoperability with specific ventilators for display (only) of selected ventilator measurement values.</p> <p>No alarms or control functionality supported.</p>	Connection of Infinity® M540 to Infinity® Medical Cockpit (display that also connects with data from networked applications and hospital systems).	Subject device provides one-way connectivity options for display (only) of selected values from specific third-party devices.
Performance characteristics – Non-clinical / Bench Test			

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Respiratory Rate (RRi): Measurement method (units)	Impedance based (bpm)	Impedance based (bpm)	Equivalent
Respiratory Rate (RRi): Display Range	5 – 60 bpm	0 – 150 bpm (measurement range)	Lower range for subject device because respiratory rate is for adolescent to adult patients only
Respiratory Rate (RRi): Resolution	1 bpm	1 bpm	Equivalent
Respiratory Rate (RRi): Accuracy (A _{rms})	± 2 bpm over 5 – 60 bpm	@ 0-100 breaths/minute: +/- 2 breaths/minute or +/- 2% of the rate value (whichever is greater) @ 101-150 breaths/minute: +/- 3 breaths/minute or +/- 3% of the rate value (whichever is greater)	The range of BPM is smaller than the reference, because the subject device is limited to adult respiratory rates and not intended for use as an apnea monitor. For the expected range for adults the accuracy is similar.
Respiratory Rate (RRi): Alarm	Not available	Acoustic and optical alarm signals for upper and lower respiration rate (user-selectable).	The subject device is an adjunctive device whereas the reference is a primary care device and alarms are needed.
Trends for RR	Yes	Yes	Similar displays