June 11, 2026

Edwards Lifesciences, LLC
Manthan Damani
Senior Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K251326
Trade/Device Name: Respiration Rate algorithm
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: May 8, 2026
Received: May 8, 2026

Dear Manthan Damani:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.06.11 10:51:39 -04'00'

For

Rachana Visaria, 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

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)*
K251326

Device Name
Respiration Rate (RR) algorithm

Indications for Use *(Describe)*
The Respiration Rate algorithm is indicated for continuous measurement of respiration rate in patients over 18 years of age using compatible non-invasive blood pressure finger cuffs or compatible minimally invasive blood pressure sensors during no motion conditions in environments where health care is provided by clinicians.

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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K251326

510(k) Summary – Respiration Rate (RR) Algorithm

Sponsor:	Edwards Lifesciences, LLC One Edwards Way Irvine, CA 92614
Establishment Registration Number:	2015691
Contact Person:	Manthan Damani Senior Manager, Regulatory Affairs One Edwards Way Irvine, CA 92614 Phone: 949-628-0406 manthan.damani@bd.com
Date:	June 5, 2026
Trade Name:	Respiration Rate (RR) algorithm
Regulation Name/ Number:	Breathing frequency monitor 21 CFR 868.2375
Product Code:	BZQ, Class II
Primary Predicate:	Covidien Nellcor Respiration Rate Software Application, K111933 (Breathing Frequency Monitor, 21 CFR 868.2375, BZQ, Class II)
Reference Device:	HemoSphere Advanced Monitoring Platform, K223865 (Programmable Diagnostic Computer, 21 CFR 870.1425, DQK, Class II)

Device Description:

The Respiration Rate (RR) algorithm is intended for continuous measurement of respiration rate in patients in environments where health care is provided by clinicians.

The Respiration Rate (RR) algorithm captures the respiratory modulation of the Arterial Blood Pressure (ABP) signal by processing specific beat-to-beat parameters of the ABP signal from which RR is then computed. The Respiration Rate (RR) algorithm quantifies respiration rate in breaths per minute (BPM) based on the ABP signal acquired from existing previously cleared Edwards' non-invasive blood pressure finger cuff: ClearSight™, Acumen IQ™, and VitaWave™, or minimally invasive blood pressure sensor: TruWave™, FloTrac™, and Acumen IQ™.

Indications for Use:

The Respiration Rate algorithm is indicated for continuous measurement of respiration rate in patients over 18 years of age using compatible non-invasive blood pressure finger cuffs or compatible minimally invasive blood pressure sensors during no motion conditions in environments where health care is provided by clinicians.

Comparison to Predicate Device:

The subject device and the primary predicate device, have the following key similarities:

- Both devices have similar intended use and indication for use for continuous measurement of respiration rate.
- Both devices have the same performance accuracy as it relates to measurement of respiration rate.

The subject device and the primary predicate, have the following key differences:

- Subject device technology is based on measurement of Respiration Rate using arterial blood pressure signal, while the primary predicate technology is based on measurement of Respiration Rate (RR) using photoplethysmography/ pulse-oximetry. However, the arterial blood pressure signal, indicating the pulsatile pressure in the blood vessel, and the photoplethysmography signal, indicating the changes of volume of the vessel as a result of the pulsating pressure in the vessel, are physiologically closely related. As such, Respiration Rate derived from either the arterial blood pressure signal or the photoplethysmography signal are very similar.

- The subject device utilizes the reference device, HemoSphere Advanced Monitoring Platform (K223865, cleared June 9, 2023) as support for the difference in technology used between the subject (arterial blood pressure signal acquired using existing non-invasive blood pressure finger cuffs, or

existing minimally invasive blood pressure sensors) and primary predicate device (pulse-oximetry based signal acquired using pulse-oximetry sensor).

The HemoSphere Advanced Monitoring Platform when used in conjunction with compatible non-invasive blood pressure finger cuffs (ClearSight™, Acumen IQ™, and VitaWave™) or with compatible minimally invasive blood pressure sensors (TruWave™, FloTrac™, and Acumen IQ™), is used to generate arterial blood pressure signals as part of the APCO (Arterial Pressure-based Cardiac Output) algorithm.

The subject respiration rate algorithm utilizes these APCO blood pressure signals as input to calculate the respiration rate. As such, the subject algorithm utilizes the same existing non-invasive blood pressure finger cuff and minimally invasive blood pressure sensor technology as well as the existing APCO algorithm as the HemoSphere Advanced Monitoring Platform for measurement of respiration rate. Successful performance testing results show no new or different concerns of safety and effectiveness for the measurement of Respiration Rate for the subject device which utilizes arterial blood pressure signal technology, and that the subject device performs as intended.

Table 1 provides a comparison of the applicable features and specifications for the subject device, primary predicate device (Covidien Nellcor Respiration Rate Software Application, v1.0), and reference device (HemoSphere Advanced Monitoring Platform).

Table 1.

Features	Subject Device (Respiration Rate algorithm)	Primary Predicate Device (Covidien Nellcor Respiration Rate Software Application, v1.0)	Substantial Equivalence
Name	Respiration Rate algorithm	Covidien Nellcor Respiration Rate Software Application, v1.0	**N/A**
510(k)	K251326	K111933 (Cleared March 15, 2012)	**N/A**
FDA Product Code, Regulation Number	**BZQ, 21 CFR 868.2375**	**BZQ, 21 CFR 868.2375** DQA, 21 CFR 870.2700 DSA, 21 CFR 870.2900	**SAME as the primary predicate device**
Device Classification	Class II	Class II	**SAME as the primary predicate**
Manufacturer	Edwards Lifesciences LLC One Edwards Way, Irvine, CA 92614	Covidien 6135 Gunbarrel Ave, Boulder, CO 80301	**N/A**
Intended Use	The Respiration Rate algorithm **is intended for measurement of respiration rate in patients** in environments where health care is provided by clinicians.	The Covidien Nellcor Respiration Rate Software Application, v1.0 **is intended for measurement of respiration rate in patients** in hospitals and hospital-type facilities.	**SAME** intended use as the primary predicate device (RR measurement) and **SIMILAR** use environments.
Indications for use	The Respiration Rate algorithm is **indicated for continuous measurement of respiration rate in patients over 18 years of age** using compatible non-invasive blood pressure finger cuffs or compatible minimally invasive blood pressure sensors during no motion conditions in environments where health care is provided by clinicians.	The Covidien Nellcor Respiration Rate Software, when used in conjunction with a Nellcor pulse oximeter and a Nellcor Respiration Rate Sensor, is **intended to be used for the continuous, non-invasive monitoring of respiration rate in adults** in hospitals and hospital-type facilities.	**SIMILAR to the primary predicate device**
Intended Use Population	Patient population over 18 years of age	Adults	**SIMILAR to the primary predicate device. The Substantial Equivalence in patients between 18 and 21 was supported by clinical validation.**

Features	Subject Device (Respiration Rate algorithm)	Primary Predicate Device (Covidien Nellcor Respiration Rate Software Application, v1.0)	Substantial Equivalence
Respiration Rate parameters measured	RR (arterial blood-pressure signal based)	RR (plethysmogram based)	**DIFFERENT. The subject device measures RR via arterial blood pressure signals previously cleared in the reference device K223865. Testing against the gold standard demonstrated equivalent accuracy in the subject device.**
Respiration Rate Range (measured in Breaths Per Minute (BPM))	4- 40 BPM	4- 40 BPM	**SAME as the primary predicate device**
Respiration Rate Accuracy	A_{RMS} / RMSE ≤ 3 BPM, Bias / Mean Error within ± 1 BPM Bland-Altman LoA 95% CI within ± 3 bpm	RMSD < 3 BPM, Mean Error of ± 1 BPM	**SAME as the primary predicate device**
Mode of Operation	Non-invasive, continuous measurements using compatible non-invasive blood pressure finger cuffs (ClearSight, Acumen IQ, VitaWave). Minimally invasive, continuous measurements using compatible minimally invasive blood pressure sensors (TruWave, FloTrac, Acumen IQ).	Non-invasive, continuous measurements using pulse-oximetry sensors	**SAME as the primary predicate**
Principle/ Method of Operation	Respiration Rate algorithm calculates Respiration Rate from arterial blood pressure signal obtained using compatible non-invasive blood pressure finger cuff sensors (ClearSight, Acumen IQ, VitaWave) or compatible minimally invasive blood pressure sensors (TruWave, FloTrac, Acumen IQ).	Respiration Rate calculated using photoplethysmography waveform obtained using compatible sensors.	**DIFFERENT. The subject device has the same principle of operation (arterial blood pressure signal) previously cleared in reference device K223865. This does not raise new questions of safety and effectiveness.**
Type of Sensor used	Non-invasive blood pressure finger cuffs (ClearSight, Acumen IQ, VitaWave). Minimally invasive blood pressure sensors (TruWave, FloTrac, Acumen IQ).	Non-invasive pulse oximetry sensor	**DIFFERENT. The subject device has the same principle of operation (arterial blood pressure signal) previously cleared in reference device K223865. Testing against the gold standard demonstrated equivalent accuracy in the**

Features	Subject Device (Respiration Rate algorithm)	Primary Predicate Device (Covidien Nellcor Respiration Rate Software Application, v1.0)	Substantial Equivalence
			subject device. This does not raise new questions of safety and effectiveness.

Performance Data (Bench and/or Clinical)

The following verification activities were performed for ensuring the safety and effectiveness of the subject Respiration Rate algorithm and to support substantial equivalence of the Respiration Rate algorithm to its primary predicate, Covidien Nellcor Respiration Rate Software Application v1.0, to the additional predicate, HemoSphere Advanced Monitoring Platform, and to reference data from: Capnostream 35 Portable Respiratory Monitor, Intellivue MX 750 with Microstream CO2 Extension, Aisys CS2, Primus US Apollo.

Software Verification and Validation Testing

Software verification and validation was performed per IEC 62304, Medical Device Software - Software Life Cycle Processes, ISO 14971, Medical devices- Application of risk management to medical devices, and FDA's Guidance Document for Industry and FDA Staff on 'Content of Premarket Submissions for Device Software Functions' (issued June 14, 2023). The Respiration Rate algorithm was tested at the algorithm level to ensure the safety of the device. All tests passed.

Cybersecurity documentation and testing were performed for the Respiration Rate algorithm to address cybersecurity requirements in accordance with FDA Guidance Document 'Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions' (issued February 3, 2026). Cybersecurity documentation included cybersecurity architecture decomposition, cybersecurity threat analysis, cybersecurity requirements, cybersecurity controls, cybersecurity management plan, cybersecurity risk analysis, cybersecurity Software Bill of Materials, security SCA and SAST reports. Cybersecurity testing included security testing of software requirements, vulnerability assessment, third-party penetration testing, verification of control effectiveness. All cybersecurity risks were mitigated to an acceptable risk level based on the cybersecurity risk assessment.

Clinical Performance Testing

Retrospective analyses were performed on human data collected from randomly selected 71 hospitalized patients and volunteers, under spontaneous breathing (breathing without any external mechanical support) and mechanically ventilated (breathing using a mechanical ventilator) across 6 US and EU sites, independent of the device development. Respiratory rate was derived from compatible, FDA-cleared non-invasive blood pressure finger cuffs and minimally invasive blood pressure sensors. The accepted gold standard - blinded, manually-counted end-tidal CO2

waveforms - was used for spontaneously breathing patients. Ventilator output was used as the gold standard comparator for ventilated patients. Simulated ABP data was performed to bridge the gap and cover the entire claimed RR range (4-40 bpm).

Accuracy of the Respiration Rate (RR) algorithm was calculated using the ground truth and Bland-Altman Analysis. The 95% Confidence Interval (CI) of the Limits of Agreement (LoA) was within ± 3 bpm. Additionally, the results demonstrated the subject device met acceptance criteria of ARMS / RMSE ≤ 3 BPM and Bias / Mean Error within ± 1 BPM (which is the same accuracy as that of the primary predicate) and performed equally well across the intended use population for different demographic factors (race, ethnicity, age, gender, BMI, skin pigmentation, comorbidities) and sites, thereby showing substantial equivalence to the predicate.

Algorithm performance testing for the subject Respiration Rate algorithm also included verification of RR algorithm specifications, RR algorithm code review, and RR algorithm software GUI display and integration on a laptop.

Conclusion

The subject Respiration Rate (RR) algorithm has successfully passed functional and performance testing, including software and algorithm verification and validation. Completion of all performance verification and validation activities demonstrated that the subject device meets its predetermined design and performance specifications. Verification activities performed confirmed that the differences in the features did not adversely affect the safety and effectiveness of the subject device, and that the subject device performs as intended. The testing performed demonstrates that the Respiration Rate (RR) algorithm is substantially equivalent to its legally marketed predicate device.