May 12, 2026

CorVent® Medical, Inc.
Amed Ayubi
Vice President of Regulatory and Quality
4837 Amber Valley Pkwy. S Suite #2
Fargo, North Dakota 58104

Re: K260051
Trade/Device Name: CorVision® (91-205-Z0014)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MOD
Dated: April 8, 2026
Received: April 8, 2026

Dear Amed Ayubi:

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,

John S. Bender -S

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

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)*
K260051

Device Name
CorVision®

Indications for Use *(Describe)*
CorVision® is only compatible with and intended for use exclusively with the CorVent® RESPOND® Ventilator (K241135) by qualified, trained personnel under the direction of a licensed clinician. This application wirelessly interfaces with the RESPOND® Ventilator to receive data and provides a supplemental display of ventilator parameters, settings, measurements, status, waveforms, and event log information. The application operates in read-only mode and has no ventilator settings or alarm control functions. The RESPOND® Ventilator is intended for pediatrics through adult patients weighing at least 38 kg (84 lbs).

CorVision® is intended for use in hospital and institutional environments, including intra-hospital transport, long-term acute care, skilled nursing facilities, long-term care, and subacute care facilities (same as the RESPOND® Ventilator). CorVision® is intended to supplement and not replace any part of the current ventilator monitoring procedures.

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	March 31, 2026
Submitter	CorVent® Medical Inc. 4837 Amber Valley Pkwy S, Suite #2 Fargo, ND 58104 (443) 928-9195
Submitter Contact	Amed Ayubi VP of Regulatory and Quality Management Representative & PRRC P: 937-728-3704 E: aayubi@corventmedical.com
Device Name	CorVision®
Device Regulation Number	868.5895
Device Regulation Name	Continuous Ventilator
Device Product Code	MOD
Device Product Code Name	Accessory to Continuous Ventilator (Respirator)
Device Regulatory Class	Class II
Predicate Device Name	Care Cycle Connect Application – K161411
Predicate Regulation Number	868.5895
Predicate Regulation Name	Continuous Ventilator
Predicate Product Code	MOD
Predicate Product Code Name	Accessory to Continuous Ventilator (Respirator)
Predicate Regulatory Class	Class II

1. Indications for Use

CorVision® is only compatible with and intended for use exclusively with the CorVent® RESPOND® Ventilator (K241135) by qualified, trained personnel under the direction of a licensed clinician. This application wirelessly interfaces with the RESPOND® Ventilator to receive data and provides a supplemental display of ventilator parameters, settings, measurements, status, waveforms, and event log information. The application operates in read-only mode and has no ventilator settings or alarm control functions**.** The RESPOND® Ventilator is intended for pediatrics through adult patients weighing at least 38 kg (84 lbs).

CorVision® is intended for use in hospital and institutional environments, including intra-hospital transport, long-term acute care, skilled nursing facilities, long-term care, and subacute care facilities (same as the RESPOND® Ventilator). CorVision® is intended to supplement and not replace any part of the current ventilator monitoring procedures.

2. Predicate citation and legal market confirmation

Predicate device: Respironics Care Cycle Connect Application, 510(k) K161411. The predicate 510(k) decision (K161411) was cleared on 2016-10-14 and remains legally marketed in the U.S. as of the submission date of this 510(k).

3. Device Description

CorVision® is an accessory to a continuous ventilator. CorVision® is intended for use with RESPOND® Ventilator cleared by the FDA under K241135. CorVision® is a mobile iOS software accessory to the RESPOND® Ventilator. It is designed to display ventilator waveforms, parameters, settings, status and event log information in real time in the hospital and institutional - healthcare settings.

In its current implementation, CorVision® connects wirelessly to the RESPOND® Ventilator via a Bluetooth® Class 1 (BLE 5.x) interface with a nominal range of approximately 10 meters (30.8 feet). The application is compatible with iPad 9th, 10th, and Air M3 generations.

CorVision® operates in read-only mode; it transmits no commands or control data to the ventilator. All ventilator functionality, alarm management, and parameter adjustments remain exclusively under the ventilator's primary

control interface. The RESPOND® Ventilator's performance and safety functions are not altered in any way by pairing with the CorVision® .

Data is transmitted periodically from the RESPOND® Ventilator and displayed on the CorVision® for supplemental viewing by trained clinical personnel. The application is intended for use in hospital and institutional environments where the ventilator is physically present and remains the primary source of patient monitoring and alarm management.

4. Technology Comparison Summary

Data flow architecture: RESPOND® Ventilator → BLE (BLE 5.x, GATT profile, custom service UUID) → CorVision® (iPad application). CorVision® only subscribes to ventilator read-characteristics; no written characteristics are exposed.

Bluetooth details: BLE version: 5.x (specified), radio class: Bluetooth Class 1, nominal range: ~10 m. Pairing method: Out-of-box device serial-number confirmation + on-device visual ventilator ID. Pairing prevents connection to non-matching serial numbers.

Encryption and key management: Link-layer encryption using AES-128 CCM (BLE Security Mode 1, LE Secure Connections where available). Session keys are negotiated by BLE specification; no persistent long-term keys are stored outside the iOS Keychain. Keys are protected by iOS secure storage and application-level access control.

Failure modes and mitigations: BLE dropouts -> connection-loss warning and automatic reconnect attempts; wrong-device pairing -> serial number confirmation and visual ID; intercepted traffic -> AES-128 encryption and application-level payload validation; tampered app -> iOS code signing enforcement and app-store distribution. Comparison to predicate (Care Cycle Connect K161411):

Both use iOS platform and BLE with link-layer encryption. Differences: BLE version (predicate unspecified) and limited hospital-only usage for CorVision®. These differences do not alter the read-only architecture nor affect safety/effectiveness.

5. Risk Management Summary

Risk management activities were conducted in accordance with ISO 14971:2019 and AAMI TIR57, addressing system-level, software, usability, communication, and cybersecurity risks. Identified hazards included incorrect data display, BLE communication loss, wrong-device pairing, incompatible hardware/software, cybersecurity threats, and use-related risks. All hazards were mitigated through established design controls, including:

- Read-only architecture
- Serial-number confirmation and visual ventilator identification
- Encrypted BLE communication
- Connection-loss warnings
- Hardware/software compatibility enforcement
- Event logging and IFU-aligned warnings

All Risk Control Measures were verified and validated. No new hazards were introduced, and all residual risks were determined to be "Acceptable and Reduced As-Far-As-Possible (AFAP) consistent with Generally Accepted State of the Art".

Residual Risk: All identified risks were reduced as far as possible and judged acceptable based on benefit to risk analysis. Residual risks and the rationale for acceptability are documented in the Risk Management File.

6. Performance and Verification and Validation Testing

- FDA software guidance
- IEC 62304 Class A software

- IEC 62366-1
- Applicable human factors and cybersecurity standards

Testing Included:

Verification Testing	BLE pairing, encryption, data accuracy, labeling, compatibility, and design input conformance
System Validation	Accurate visualization across ventilation modes, BLE disconnection/recovery behavior, event synchronization
Usability Testing	Summative testing with Respiratory Therapists demonstrating successful completion of all critical tasks with no hazardous use errors
Reliability Testing	168 hours of uninterrupted operation
Cybersecurity Testing	No vulnerabilities identified

All testing demonstrated that CorVision® performs safely and effectively for its intended use.

7. Principle of Operation

1. RESPOND Ventilator transmits physiological and status data via BLE.
2. CorVision, as a bonded client, receives decrypts, and parses the data stream.
3. The application displays values in real-time graphical and tabular formats.
4. Users navigate between Plots, Parameters, Event Log, and System Info tabs.
5. Ventilator therapy and alarms remain unaffected by CorVision operation.

Inputs into CorVision:

- From RESPOND Ventilator (BLE 5.x, read-only):
  - Waveform data: Pressure, Flow, Volume, Leak (time-based).
  - Breath-by-breath values: Tidal Volume (Vti, Vte), Respiratory Rate (RR), Minute Ventilation (MVe), etc.
  - Ventilator settings: PEEP, FiO_2 %, Inspiratory Pressure, Tidal Volume, Backup settings, etc.
  - Alarm settings: High/low thresholds, Apnea, Disconnect, O_2 margin etc.
  - System information: Device ID, software version, serial number, operational hours, state (Run/Standby).

- From User (iPad navigation):
  - Bluetooth pairing key entry during initial setup.
  - Screen navigation (button presses, tab selection, waveform pause/resume, scaling, cursor movement).

Outputs from CorVision:

- To User (on iPad display):
  - Real-time waveform plots (Airway Pressure, Flow, Volume, Leak).
  - Loop plots (P–V, F–V).
  - Measurement and settings tiles.
  - Ventilator settings.
  - Alarm limits (visual only, no annunciation).
  - Chronological ventilator even- log (10,000 events).
  - System/device information (serial number, software build, ventilated hours).

- To RESPOND Ventilator:
  - *Ventilator Ping* (visual identification only; no effect on therapy).

Summary:

All I/O is one-way *Ventilator → CorVision* except for the optional Ping. No ventilator therapy or safety-critical controls are affected by CorVision inputs or outputs.

Accessories / Interoperability

- **Compatible System:** RESPOND Ventilator only.
- **Optional Accessory:** iPad arm and iPad securement enclosure for pairing a given iPad with a single ventilator.

Risk Controls & Cybersecurity

- **Read-only design** eliminates ventilator control risk.
- **Bonding/authentication** requires ventilator-side confirmation.
- **Encryption** via BLE AES-128/256 CCM.
- **Hazard mitigations:**
  - Communication loss – ventilator remains alarm/display master. CorVision displays messages stating communication loss.
  - Incorrect display – validated against ICD scaling; ventilator remains primary source.
  - Wrong ventilator connection – mitigated by user confirming serial number confirmation and Ping invoked RESPOND Ventilator flashing LCD.
  - iPad/app failure – ventilator unaffected; user alerted by frozen/absent data.

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8. Predicate Device Substantial Equivalence Summary

Characteristic	Subject Device: CorVent® Connect Application (CCAP)	Predicate Device: Care Cycle Connect (CCC) Application	Determination
Applicable Regulations	21CFR820 Quality System Regulation 21CFR807 Subpart E – Premarket Notification 21CFR868 Anesthesiology Devices 21CFR868:5895 Continuous Ventilator	21CFR820 Quality System Regulation 21CFR807 Subpart E – Premarket Notification 21CFR868 Anesthesiology Devices 21CFR868:5895 Continuous Ventilator	**Equivalent**
Review Panel	Anesthesiology	Anesthesiology	**Equivalent**
Device Classification	(b) Class II (Performance Standards).	(b) Class II (Performance Standards).	**Equivalent**
Classification Name	21CFR868:5895 Continuous Ventilator	21CFR868:5895 Continuous Ventilator	**Equivalent**
Device Identification	(a) Identification. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.	(a) Identification. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.	**Equivalent**
Performance Standards	General Controls & Special Controls	General Controls & Special Controls	**Equivalent**
Classification Code	MOD	MOD	**Equivalent**
Classification Code Name	Accessory to Continuous Ventilator (Respirator)	Accessory to Continuous Ventilator (Respirator)	**Equivalent**
Indications for Use	CorVision® is only compatible with and intended for use exclusively with the CorVent® RESPOND® Ventilator (K241135) by qualified, trained personnel under the direction of a licensed clinician. This application wirelessly interfaces with the RESPOND® Ventilator to receive data and provides a supplemental display of ventilator parameters, settings, measurements, status, waveforms, and event log information. The application operates in read-only mode and has no ventilator settings or alarm control functions. The RESPOND® Ventilator is intended for pediatrics through adult patients weighing at least 38 kg (84 lbs). CorVision® is intended for use in hospital and institutional environments, including intra-hospital transport, long-term acute care, skilled nursing facilities, long-term care, and subacute care facilities (same as the RESPOND® Ventilator). CorVision® is intended to supplement and not replace any part of the current ventilator monitoring procedures.	The Care Cycle Connect software application is intended for use with Trilogy Series ventilators by both caregivers and clinicians. The application pairs with the Trilogy device via a Bluetooth connection. The application provides the caregiver remote patient monitoring, and alarm surveillance. Alarm surveillance consists of both an audible tone and a visible alert if an alarm condition exists. The application provides the clinician with the ability to view, collect and store patient ventilator usage data. Care Cycle Connect (CCC) also provides educational information on ventilator use to both caregivers and clinicians. It is intended to be used in the home, and hospital/ institutional settings. The Care Cycle connect application is intended to supplement and not replace any part of the current device monitoring procedures	**Equivalent** [1]The CCAP is not intended to control or display alarms in real time (only through event log summary). [2]The CCAP is not intended to provide clinicians with educational information on ventilator use. [3]The CCAP is not intended to be used in the home environment. The differences in indication for use do not impact function and do not raise different questions of safety and/or effectiveness. Therefore, the intended use of the CCAP is **equivalent** to that of the predicate device: to provide a supplemental display of ventilator data without controlling ventilation.
User Population	Same as the RESPOND® Ventilator (cleared by FDA under K241135) is intended for use by qualified, trained personnel under the direction of a licensed clinician.	Clinicians (respiratory and non-respiratory) and physicians.	**Equivalent,** Both devices are intended for use by trained healthcare professionals (respiratory therapists, clinicians) under clinical supervision.
Hardware Install Platform	iPad 9th, 10th and/or Air M3 Generation (via Bluetooth direct connection)	Apple iPad; iPad mini (via Bluetooth direct connection)	**Equivalent**
Viewable Ventilator Patient Data			
Ventilator Settings	Yes	Yes	**Equivalent**
Ventilator/Patient Waveforms	Yes	Yes	**Equivalent**
Device Logs	Yes	Yes	**Equivalent**
Alarms	Yes (through event log summary)	Yes	**Equivalent**

Characteristic	Subject Device: CorVent® Connect Application (CCAP)	Predicate Device: Care Cycle Connect (CCC) Application	Determination
			The difference in patient data does not impact function and does not raise different questions of safety and/or effectiveness.
Application Features			
Calendar	No	Yes	**Equivalent** The difference in calendar feature does not impact function and does not raise different questions of safety and/or effectiveness.
Patient Information Record	No (CCAP does not support any entry of patient data. Nor is any patient information available from the RESPOND® Ventilator for display).	Yes	**Equivalent** The difference in patient information does not impact function and does not raise different questions of safety and/or effectiveness.
Note Taking	No (CCAP does not support any entry of data)	Yes	**Equivalent** The difference in note taking features does not impact function and does not raise different questions of safety and/or effectiveness.
Educational Reference	Yes, limited to CCAP usability (i.e., IFU, Privacy Policy, and Supplemental display).	Yes, Care Cycle Connect (CCC) Application provides its IFU, Privacy Policy, and Supplemental display information and also provides educational information on ventilator use to both caregivers and clinicians.	**Equivalent** The difference in education does not impact function and does not raise different questions of safety and/or effectiveness.
Software Application Platform	Apple iOS	Apple iOS	**Equivalent** Both devices use iOS platform security controls and Bluetooth LE with AES-128 encryption; cybersecurity verification.
Hardware Install Platform	iPad 9th, 10th and/or Air M3 Generation (via Bluetooth direct connection)	Apple iPad; iPad mini (via Bluetooth direct connection)	**Equivalent** The difference in hardware platforms does not impact function and does not raise different questions of safety and/or effectiveness.

Substantial Equivalence Discussion

The table above compares the key features of the proposed subject device with the identified predicate device. The following decision points are per FDA guidelines:

Decision 1 – Is the predicate device legally marketed? **Yes**.

Decision 2 – Do the devices have the equivalent intended use? **Yes** differences do not raise different or new questions of safety and/or effectiveness.
Rationale for differences in Indications and Features:

- **Home-use exclusion:** The subject device (CorVision®) is limited to hospital and institutional environments because pairing requires physical presence and manual serial-number confirmation with the RESPOND® ventilator; there is no remote cloud connectivity or persistent patient location tracking. This limitation reduces exposure to uncontrolled home networks and does not

change the intended use of providing a supplemental, read-only ventilator display. Supporting evidence: BLE range limitation testing (see V&V traceability table) and labeling warnings (IFU Section X).

- **Alarm functionality:** CorVision® operates in read-only mode and does not provide real-time audible alarm control. Alarms are viewable only via event-log summaries and transient waveform/parameter displays. The predicate's alarm surveillance features include audible alerts; CorVision®' lack of real-time alarm control is mitigated by design (ventilator maintains primary alarm responsibility) and does not introduce new safety questions. Supporting evidence: architecture diagrams, usability results demonstrating clinician reliance on ventilator primary interface.
- **Educational and patient data features:** CorVision® provides only device IFU and supplemental display help (limited educational content) and does not permit patient data entry or storage. This reduces the risk of misattributed patient data and does not change the device's fundamental intended purpose as a read-only display. Conclusion: Differences are limited to implementation and environment restrictions and do not raise new questions of safety and effectiveness via FDA Decision 2 guidance.

Decision 3 – Do the devices have equivalent technological characteristics? **Yes** differences do not raise different or new questions of safety and/or effectiveness.
CorVision® and the predicate both present ventilator data in a read-only fashion via iOS BLE connections and use link-layer encryption. Differences in BLE version, platform generation, and environmental use (hospital-only vs. predicate home/hospital) are implementation differences that do not raise new questions of safety or effectiveness.

Based on the review and assessment of table above Subject Device vs Predicate Device Comparison Analysis, Determinations, and the answers to decisions 1, 2, and 3 are **YES**, the Respironics **Care Cycle Connect (CCC) Application** is a valid **"Predicate Device",** and the **CorVent® Connect Application (CCAP) is** considered to be **"Substantially Equivalent to the Care Cycle Connect (CCC) Application ("The Predicate")"** and differences do not raise different or new questions of safety and/or effectiveness.

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9. Conclusion

The CorVision® software is a read-only accessory intended to display ventilator data and does not alter the intended use, performance, alarm behavior, or control functions of the RESPOND® Ventilator. Differences between the subject device and the predicate are limited to implementation details that do not raise new questions of safety or effectiveness.

Comprehensive risk management, verification, validation, usability, reliability, and cybersecurity testing demonstrate that CorVision® meets all applicable design and performance requirements and performs as intended in its clinical environment.

Based on equivalent intended use, comparable technological characteristics, and satisfactory performance data, **CorVision® is substantially equivalent to the Care Cycle Connect App predicate device**.

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