March 17, 2026

Compal Electronics, Inc.
Casper Chen
Senior Director
No. 581 and 581-1, Ruiguang Rd., Neihu Dist.
Taipei City, 11492
Taiwan

Re: K252078
Trade/Device Name: BreathePal Bilevel (GFM50-MD2201)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MNS
Dated: February 26, 2026
Received: February 26, 2026

Dear Casper Chen:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
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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)*
K252078

Device Name
BreathePal Bilevel

Indications for Use *(Describe)*
The BreathePal Bilevel is intended to provide non-invasive ventilator (NIV) support for adult patients weighing over 30 kg (66lbs) who suffer from Obstructive Sleep Apnea (OSA) and Respiratory Impairment. It is intended for use in both home and clinical environment, including hospitals, sleep laboratories, and sub-acute care institutions.

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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510(k) Summary

Submitter

510(k) Owner — Compal Electronics, Inc.
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Official Correspondent — Casper Chen
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Date of Preparation — March 16, 2026

Device

Trade Name	BreathePal Bilevel
Common/ Generic Name	Ventilator, Continuous, Non-Life-Supporting
Device Classification	Class II
Regulation Number	21 CFR 868.5895
Classification Name	Continuous Ventilator
Product Code	MNS

Primary Predicate Device — BiPAP A30 Ventilatory support system (K113053)

Device Description

BreathePal Bilevel devices are blower-based positive airway pressure systems designed to provide non-invasive ventilation only. These devices deliver two distinct pressure levels: a higher pressure during inhalation (IPAP) and a lower pressure during exhalation (EPAP). This pressure differential facilitates the flow of air into and out of the lungs. The system can also be configured to provide a single, constant pressure level, known as Continuous Positive Airway Pressure (CPAP).

The BreathePal Bilevel utilizes a microprocessor-controlled blower along with integrated pressure and flow sensors to detect patient breathing patterns and deliver precise therapeutic pressure. The device includes a comprehensive alarm system, featuring both therapeutic alerts (e.g., large leak) and technical alarms (e.g., system fault). A user interface allows for the adjustment of clinical parameters and the display of monitored therapy data. Additionally, the device features comfort settings, such as iBreath (FLEX), which provides adaptive pressure relief during the initial phase of exhalation to enhance patient comfort.

Indication for Use

The BreathePal Bilevel is intended to provide non-invasive ventilator (NIV) support for adult patients weighing over 30 kg (66 lbs) who suffer from Obstructive Sleep Apnea (OSA) and Respiratory Impairment. It is intended for use in both home and clinical environment, including hospitals, sleep laboratories, and sub-acute care institutions.

Performance Testing Data

BreathePal Bilevel has completed appropriate testing, all device requirements, any mitigations required for a risk assessment, and demonstrated substantial equivalence to the predicate.

The non-clinical bench performance testing was conducted for performance validation and applied technology comparison to support substantial equivalence. The testing assessed the essential performance of the ventilator, meeting the requirements of ISO 80601-2-79.

General Safety, Electrical Safety and Electromagnetic Compatibility (EMC)

This device has been tested to appropriate ISO and IEC standards passing all test protocols. The BreathePal Bilevel was designed and tested according to:

- IEC 60601-1:2020 (Basic Safety)
- IEC 60601-1-2:2020 (EMC)
- IEC 60601-1-6:2020 & IEC 60601-1-8:2020
- IEC 60601-1-11:2020 (Home Healthcare)
- ISO 80601-2-79:2018 (Ventilatory Support)
- ISO 80601-2-74:2021 (Humidifier)

Biocompatibility Testing

The biocompatibility evaluation for the BreathePal Bilevel was conducted in accordance with ISO 10993-1:2018 and FDA's recognized consensus standards. The device has proven to be biocompatible when tested in its final, finished form. Specific evaluation of the breathing gas pathways was performed according to ISO 18562-1:2017, ensuring that the materials do not present unacceptable risks regarding VOCs, particulate matter, or leachable substances in the gas path.

Software Testing

The BreathePal Bilevel software was developed following IEC 62304:2015, "Medical Device Software – Software Life Cycle Processes". Documentation has been provided as recommended by FDA's guidance for the content of premarket submissions for software contained in medical devices. The software is classified as having a "Moderate" level of concern. Comprehensive software verification and validation testing were performed to ensure all product requirements and safety risk mitigations were successfully implemented.

Human Factors/Usability

The BreathePal Bilevel has been evaluated through a Human Factors Engineering process in accordance with FDA's 2016 guidance. Validation study results indicate that the intended users (including patients and clinical providers) can operate the device safely and effectively in its intended use environments. The labeling, user interface, and instructions for use were found to be effective in supporting the safe use of the device for the adult population weighing over 30kg (66lbs), with all residual risks associated with usability determined to be acceptable.

Substantial Equivalence Conclusion

The technological characteristics and performance testing data provided in this premarket notification demonstrate that the BreathePal Bilevel is substantially equivalent to the legally marketed predicate device, BiPAP A30 Ventilatory support system (K113053).

The BreathePal Bilevel shares the same intended use and clinical application environments as the predicate device. Based on the results of comprehensive non-clinical bench testing, electrical safety, biocompatibility, and software validation, any technological differences between the subject and predicate devices do not raise any new questions regarding safety or effectiveness.

In conclusion, based on the side-by-side comparison and objective performance data, the BreathePal Bilevel is determined to be substantially equivalent to the predicate device.

Characteristic	BreathePal Bilevel	Predicate Device: BiPAP A30 Ventilator	Comments
510(k)		K113053	
Classification	Class II	Class II	Both the subject and predicate devices are FDA Class II medical devices.
Product code	MNS	MNS	The subject device shares the MNS product code with the BiPAP A30. It does not include the MNT code because it is not indicated for invasive use.
Indication for Use	The BreathePal Bilevel is intended to provide non-invasive ventilator (NIV) support for adult patients weighing over 30kg (66lbs) who suffer from Obstructive Sleep Apnea (OSA) and Respiratory Impairment. It is intended for use in both home and clinical environment, including hospitals, sleep laboratories, and sub-acute care institutions.	The BiPAP A30 Ventilator is intended to provide non-invasive ventilatory support to treat adult and pediatric patients weighing over 10kg (22lbs) patients with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. It is intended to be used in both the home and clinical settings, such as hospitals, sleep laboratories, sub-acute care institutions.	The device covers the core therapeutic functions of the equivalent equipment, focusing on the respiratory needs of adult patients. Their application environments are equivalent, with the only distinction being the weight range coverage to ensure the quality of treatment for a specific target audience.

Patient population	Adults	Pediatrics and Adults	Both devices maintain a consistent standard of care for adult patients. The new device is targeted at adults weighing over 30 kg, which represents a subset of the original reference device's indications. This adjustment ensures that existing safety levels are maintained in clinical applications.
Environment	home, institutional/ hospital	home, institutional/ hospital	All devices are intended for use in home and institutional/hospital environments.
Sterile	Non-sterile	Non-sterile	All devices are supplied non-sterile.
Prescription status	Prescription	Prescription	All devices are prescription-only.
Principle of Operation	Microprocessor controlled Electronically powered Software driven	Microprocessor controlled Electronically powered Software driven	All devices utilize microprocessor-controlled, electronically powered, and software-driven operation.
Delivery method to patient	Continuous or intermittent positive pressure ventilation	Continuous or intermittent positive pressure ventilation	All devices deliver continuous or intermittent positive pressure ventilation.
Energy Used for device	AC and DC (Battery) Power 100 – 240 VAC, 50 - 60 Hz	AC and DC (Battery) Power 100 – 240 VAC, 50 - 60 Hz	All devices operate on AC (100–240 VAC) and DC (Battery) power sources.
Battery	External Battery	External Battery	All devices support the use of an external battery.
Humidifier	Humidifer cannot be used with a battery.	Humidifer can be used with a battery.	The subject device disables the humidifier on battery power to conserve energy for ventilation. This design choice prioritizes the critical function (ventilation) over comfort (humidification) during power loss, reducing the risk of premature battery depletion.

Humidifier of Usage	Resuable	Resuable	All devices utilize reusable humidifiers.
Capacity of Humidifier Fill Volume	330 ml	325 ml	The fill volumes are nominally equivalent (5ml difference). This negligible difference does not impact the duration of humidification or introduce new risks regarding water spillage.
Type of Water	Distilled Water	Distilled Water	Both specify distilled water to prevent mineral buildup. This minimizes the risk of bacterial growth and device scaling, consistent with the predicate device.
Humidifier setting	0-5	0-5	All devices offer a humidifier setting range of 0 to 5.
Design	Microprocessor valve controlled DC blower motor design	Microprocessor valve controlled DC blower motor design	All devices employ a microprocessor valve-controlled DC blower motor design.
Pressure Regulation Method	Pressure and flow feedback	Pressure and flow feedback	All devices utilize pressure and flow feedback for regulation
Therapy Types	Non-Invasive Mechanical ventilation	Non-Invasive Mechanical ventilation	The subject device is equivalent to the BiPAP A30.
Performance	Met ISO 80601-2-79 requirements on essential performance of ventilators	ISO 10651-6 (This standard has been revised by ISO 80601-2-79:2018 and ISO 80601-2-80:2018)	The subject device complies with the most current standard (ISO 80601-2-79). Compliance with the newer standard demonstrates a higher or equivalent level of safety and essential performance.
Duration and type of contact	Assessing biocompatibility within gas pathway.	Assessing biocompatibility within gas pathway.	All devices assess biocompatibility within the gas pathway.
Therapy Mode	-CPAP -S -S/T -T -PC	-CPAP -S -S/T -T -PC	The subject device includes the standard ventilation modes found in the predicate. It excludes the proprietary AVAPS-AE

		-AVAPS-AE	mode. The absence of this complex mode simplifies the device and eliminates risks associated with automated algorithm adjustments, without compromising standard therapy efficacy.
IPAP	4~30 cmH_2O	4~30 cmH_2O	The subject device pressure range is equivalent to that of the A30, and safety is maintained via the "High Pressure" alarm and software limits that prevent pressure from exceeding safe limits for non-invasive interfaces.
EPAP	4~25 cmH_2O	4~25 cmH_2O	The range is equivalent. Comparative testing confirms the device maintains PEEP effectively across this range, ensuring airway patency.
CPAP	4~20 cmH_2O	4~20 cmH_2O	The range is equivalent. Performance testing confirms pressure stability is maintained within specifications, presenting no new risks.
Pressure Accuracy	±2.5 cmH_2O of the setting	±2.5 cmH_2O of the setting	The accuracy specification is equivalent. Bench testing verifies that the subject device meets this tolerance under dynamic conditions, ensuring clinical effectiveness is not compromised.
Pressure Accuracy (Static)	±1.0 cm H_2O	N/A	The subject device provides a specific static accuracy claim. This tighter specification allows for more precise calibration checks, potentially improving risk management regarding device verification.
Alarm	-Circuit Disconnect Alarm - Apnea Alarm - High Respiratory Rate Alarm - Low Minute	-Circuit Disconnect Alarm - Apnea Alarm - High Respiratory Rate Alarm - Low Minute	The alarm configuration of the subject device is similar in functionality to that of the predicate, ensuring a consistent user experience and safety standard. Apart

	Ventilation Alarm - Loss of Power - Ventilator Inoperative Alarm - Low Battery Alarm - Pressure Regulation Alarm - Low Circuit Leak Alarm - High Temperature Alarm - AC Power Disconnected Alarm - Replace Detachable Battery Alarm - Insert SD Card Alarm	Ventilation Alarm - Low Tidal Volume Alarm - Loss of Power - Ventilator Inoperative Alarm - Low Battery Alarm - Pressure Regulation Alarm - Low Circuit Leak Alarm - High Temperature Alarm - AC Power Disconnected Alarm - Keypad Stuck Alarm - Replace Detachable Battery Alarm - Insert SD Card Alarm	from the two specific exclusions detailed below, all integrated monitoring alerts remain equivalent in scope and performance. 1. Keypad Stuck Alarm The BreathePal utilizes mechanical buttons engineered to eliminate the risk of jamming, a distinct improvement over the membrane-style keys found on the predicate. Because the hardware design inherently prevents the failure mode this alarm was intended to detect, its removal does not compromise device safety. 2. Low Tidal Volume Alarm This alarm is specific to volume-guaranteed modes (such as AVAPS-AE), which are not offered by the subject device. As the device operates under different ventilation parameters, this specific alert is not applicable. Essential patient safety is fully preserved through the Minute Ventilation and Apnea alarms, which provide the necessary clinical oversight for the device's intended modes.
Humidifier type	Integrated Humidifier	Integrated Humidifier	The integration method is equivalent. Electrical safety testing ensures the integration poses no thermal or leakage risks to the patient.
Chamber use duration	1 year	N/A	Defining a 1-year service life allows the user to replace the chamber before material degradation occurs. This mitigates risks of cracks or leaks that might occur with

			undefined usage durations.
Cleaning, and disinfection	-70% Isopropyl Alcohol	-70% Isopropyl Alcohol -cloth with chlorine bleach (8.3% sodium hypochlorite)	The subject device specifies 70% Isopropyl Alcohol. Validated cleaning studies demonstrate that this method effectively disinfects the device without degrading the materials, ensuring infection control risks are managed.
Tidal volume	Set Target Tidal Volume Range: N/A, Displayed Parameter Range: Greater of ± 20 ml or ± 20% of reading (0 to 2000 ml)	Set Target Tidal Volume Range: 200 - 1500 ml, Displayed Parameter Range: Greater of ± 20 ml or ± 20% of reading (0 to 2000 ml)	The BreathePal Bilevel and the predicate device share the equivalent accuracy for the Displayed Parameter Range. While the predicate device allows for a Set Target Tidal Volume (200 - 1500 ml), the BreathePal Bilevel does not support a target volume setting (N/A). This difference in clinical functionality (lack of volume-targeted ventilation) does not raise new questions of safety or effectiveness, as the BreathePal operates as a standard Bilevel pressure-controlled device. Monitoring accuracy remains equivalent to the predicate.
Breath rate	0 to 40 BPM, greater of ±1 BPM or ±10% of setting	0 - 40 BPM, greater of ± 1 BPM or ±10% of setting	The range and accuracy are equivalent. Essential performance testing confirms the device triggers and cycles accurately at these rates, preventing patient-ventilator asynchrony.
Ramp length	0 - 45 minutes	0 - 45 minutes	The ramp feature is equivalent. Clinical evaluation indicates this duration allows for patient comfort without delaying effective therapy, posing no risk to therapy efficacy.

pressure relief	FLEX (iBreath): 1 (less) to 3 (most)	Flex: 1 (less) to 3 (most)	The "iBreath" feature functions in an equivalent manner to "Flex" by reducing pressure during exhalation. Waveform analysis confirms the pressure drop is physiological and does not compromise the EPAP needed to maintain airway patency.
Detect volume and adjust Pressure	N/A	AVAPS-AE	The subject device does not automatically adjust pressure based on tidal volume. This removes the risk of algorithm-induced pressure swings. The device relies on fixed pressure support (S/T, PC), which is the standard of care for the indicated population.
Inspiratory time	0.5-3 sec.	0.5-3 sec.	The setting range is equivalent. This range is sufficient to manage the respiratory needs of the indicated patient population without risking air trapping (auto-PEEP).
Dimensions	21.9cm x21.4cm x 18.3cm	22.2cm x18.4cm x 10.8cm	The dimensions are comparable. The form factor does not affect clinical performance. Stability testing ensures the device remains upright during use, mitigating tipping risks.
Weight	2.1 kg (with humidifier) 2.5 kg (with battery)	2kg	The slight weight increase is due to the robust design. Drop and vibration testing confirms the device withstands transport stresses, ensuring the weight does not compromise mechanical integrity.