January 15, 2025

BMC Medical Co., Ltd.
Amy Wang
Regulatory Affairs Specialist
Room 10, 17F, Building 4, Huiya Plaza, No.16 Lize Road
Fengtai District
Beijing, 100073
China

Re: K242935
Trade/Device Name: Respiration Data Management Software
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 13, 2024
Received: December 13, 2024

Dear Amy Wang:

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,

Rachana Visaria -S

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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242935

Device Name

Respiration Data Management Software

Indications for Use *(Describe)*

Respiration Data Management Software is installed in a computer to perform patient management by treatment data viewing, treatment data reporting and remotely adjusting the prescribed compatible BMC CPAP and BPAP devices' settings. It is intended for healthcare professionals in healthcare facilities use only.

Type of Use *(Select one* or *both,* as *applicable)*

X 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Device Trade Name	Respiration Data Management Software
Model	PAP Link PC
Common/Usual Name	Respiration Data Management Software
Date Prepared	September 25, 2024
Sponsor Identification	BMC Medical Co., Ltd. Room 10, 17F, Building 4, Huiya Plaza, No.16 Lize Road, Fengtai District, 100073 Beijing, PEOPLE'S REPUBLIC OF CHINA
Submission Correspondent	Amy Wang BMC Medical Co., Ltd. Phone 86-18701556244 Fax 86-22-82939881 Email wangliping@bmc-medical.com
Establishment Registration #	3008566132 BMC Medical Co., Ltd. Room 10, 17F, Building 4, Huiya Plaza, No.16 Lize Road, Fengtai District, 100073 Beijing, PEOPLE'S REPUBLIC OF CHINA
Classification	Class II Device (21 CFR 868.5905)
Classification Name	Noncontinuous ventilator
Classification Panel	Medical Device
Products Code	BZD, MNS
Medical Specialties	Anesthesiology
Predicate Device(s)	ResScan (K140054)
Reason for Submission:	New Device

Indications for Use	Respiration Data Management Software is installed in a computer to perform patient management by treatment data viewing, treatment data reporting and remotely adjusting the prescribed compatible BMC CPAP and BPAP devices' settings. It is intended for healthcare professionals in healthcare facilities use only.
Device Description	The Respiration Data Management Software is a software-only device, which allows physicians and other clinical staff to transmit, analyze and review respiration data from the compatible CPAP and BPAP devices (non-life support systems), thus to assist the users in patient management and follow-up work. This also includes remote modification of the treatment parameters of the compatible devices. It can also store patient data, upload data to the cloud platform, generate and print reports.

Substantial Equivalence:

The subject and predicate devices are substantially equivalent in the following aspects:

- Same Indications for Use
- Similar operating principle
- Similar technological characteristics

Comparison of Technological Characteristics with the Predicate Device:

	Subject Device	Predicate Device	
	Respiration Data Management Software (K242935)	**ResScan (K140054)**	**Comparison**
Classification			
Device Classification	Class II Device	Class II Device	Equivalent
Classification Panel	Anesthesiology	Anesthesiology	Equivalent
Regulation Number& Product Code	21 CFR 868.5905, BZD Non continuous ventilator 21 CFR 868.5895, MNS Continuous Ventilator	21 CFR 868.5905, BZD Non continuous ventilator 21 CFR 868.5895, MNS Continuous Ventilator 21 CFR 868.5895, MNT Continuous Ventilator 21 CFR 868.5895, CBK Ventilator, continuous, facility use	The regulation number & product code depends on the compatible devices. Both the subject device and predicate device are compatible with BZD and MNS devices. The predicate device includes more compatible product codes. This difference does not raise new risks to the subject device.
Regulation Name	Noncontinuous ventilator	Noncontinuous ventilator	Equivalent
Intended Use and Indications for Use			
Intended Use of the Device	Respiration Data Management Software is installed in a computer to perform patient management by treatment data viewing, treatment data reporting and remotely adjusting the prescribed compatible BMC CPAP and BPAP devices' settings. It is intended for healthcare professionals in healthcare facilities use only.	ResScan is intended to augment the standard follow-up care of patients by providing transfer of machine and therapeutic information. This includes the ability to remotely change settings in non-life support devices only. It is intended to be used by Clinicians in conjunction with ResMed compatible therapy devices, using ResMed's proprietary communications protocol.	Equivalent
Environment of Use	Professional healthcare facilities	Professional healthcare facilities	Equivalent
Patient Population	Not for patient use. For healthcare professionals use only.	Not for patient use. For healthcare professionals use only.	Equivalent
Performance			
Application Type	PC-based software program	PC-based software program	Equivalent

Operating System	Microsoft Windows	Microsoft Windows	Equivalent
Functionality	Display of therapy data Generate reports Settings management Patient management Upload Data	Display of therapy data Generate reports Settings management Patient management	Most functions of the subject device are equivalent to the predicate device. The subject device includes a data upload function than the predicate device. Users can upload the data to the cloud platform (K160127). Software V&V testing and cybersecurity testing demonstrates safety and effectiveness of this function.
Compatible flow generators	BMC compatible therapy devices (BZD, MNS)	ResMed compatible therapy devices (BZD, MNS, MNT and CBK)	Both the subject device and predicate device are compatible with the devices with BZD and MNS product codes. The predicate device includes more compatible product codes. This difference does not raise new risks to the subject device.
Communication medium	Serial connection Removable medium Wireless medium (TCP/HTTPS)	Serial connection Removable medium	The subject device can wirelessly upload data to the cloud platform (K160127), as well as download the software upgrade package from the cloud platform. Software V&V testing and cybersecurity testing demonstrates safety and effectiveness of these functions.
Patient information	Mask Leak AHI Pressure Minute Ventilation Respiratory rate	Mask Leak AHI Pressure Minute Ventilation Respiratory rate	Equivalent
Range for patient parameters	Depends on the compatible CPAP devices	Depends on the compatible CPAP devices	Equivalent

Changeable settings	Initial Pressure Set Pressure Ramp time Humidifier level	Start Pressure Set Pressure Ramp time Setting time	Equivalent. Remote setting change functionality only applies to non-life support devices. Changeable settings of the subject device and the predicate device are similar. Difference does not raise new risks.
Changeable setting range	Depends on the compatible CPAP devices	Depends on the compatible CPAP devices	Equivalent

Non-Clinical Data

The following non-clinical data were used in support of the substantial equivalence determination.

Software Verification and Validation

Software verification and validation were conducted and documentation was provided in accordance with FDA's Guidance "Content of Premarket Submissions for Device Software Functions".

Cybersecurity

Cybersecurity was considered and evaluated in accordance with FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Conclusion

The subject device Respiration Data Management Software has the same intended use and similar technological characteristics as the predicate device. Differences in the technological characteristics between the subject device and predicate device do not raise new/different questions of safety or effectiveness. Thus, the subject device is substantially equivalent to the predicate device.