December 5, 2022

BMC Medical Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K213169
Trade/Device Name: BPAP System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: MNS
Dated: December 5, 2022
Received: November 4, 2022

Dear Diana Hong:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

for James Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213169

Device Name
BPAP System

Indications for Use *(Describe)*
The BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with Obstructive Sleep Apnea (OSA) or Respiratory Insufficiency. The integrated humidifier is indicated for the humidification and warming of air from the flow generator device. The device is intended for adult patients weighing more than 66lbs (30 kg) by prescription. The device is intended for single patient use in the home environment and multi-patient re-use in the hospital/institutional environment.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K213169

1. Date of Preparation: 12/05/2022

2. Sponsor Identification

BMC Medical Co., Ltd.
Room 901, Building 1, No.28 Pingguoyuan Road, Shijingshan, Beijing 100041, CHINA

Establishment Registration Number: 3008566132

Contact Person: Fang Zheng
Position: Director of Regulatory Affairs & Quality Assurance
Tel: +86-10-5166 3880
Fax: +86-10-5166 3880-810
Email: zhengfang@bmc-medical.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: BPAP System
Common Name: Continuous ventilator

Regulatory Information
Classification Name: Continuous Ventilator
Classification: II
Product Code: MNS
Regulation Number: 21 CFR 868.5895
Review Panel: Anesthesiology

Indication for Use Statement:

The BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with Obstructive Sleep Apnea (OSA) or Respiratory Insufficiency. The integrated humidifier is indicated for the humidification and warming of air from the flow generator device. The device is intended for adult patients weighing more than 66lbs (30 kg) by prescription. The device is intended for single patient use in the home environment and multi-patient re-use in the hospital/institutional environment.

Device Description

The proposed device is a non-invasive, continuous positive airway pressure ventilator, incorporating a heated respiratory humidifier. The device is intended to treat obstructive sleep apnea or respiratory insufficiency by delivering a flow of positive airway pressure at a level prescribed by a physician to splint open the airway and prevent airway collapse.

The proposed device is available in different models designed with different therapy modes and pressure ranges. The therapy modes are available in six types, which are CPAP, Spontaneous (S), Spontaneous/Timed (S/T), Timed (T), Auto CPAP and Auto S. The pressure range for the proposed devices is available in two types, which are 4-25cm H_2O and 4-30 cm H_2O. The designated pressure range and therapy mode for each proposed model was provided in following table

Model	Work Mode	Pressure Range
G3 B25VT	CPAP, S, T, S/T	4-25 cm H_2O
G3 B30SV	CPAP, S/T	4-30 cm H_2O
G3 B30VT	CPAP, S, T, S/T	
G3 LAB	CPAP, Auto CPAP, S,	

	Auto S, T, S/T	

Alarm module is incorporated in the device. The device will generate audio and visual alarm for any abnormal conditions. The proposed device is provided non-sterile, and not to be sterilized by the user prior to use. The proposed device can be reused by single patient and multi-patients

5. Identification of Predicate Device

510(k) Number: K153061
Product Name: Juno VPAP ST-A

6. Identification of Secondary Predicate Device

510(k) Number: K201620
Product Name: Luna®G3 BPAP 25A

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- AAMI/ANSI/ES60601-1: 2005/(R)2012 And A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-8:2006+A1: 2012 Medical Electrical Equipment–Part 1-8: General requirements for basic safety and essential performance-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11:2015 Medical Electrical Equipment–Part 1-11: General requirements for basic safety and essential performance-Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 80601-2-70: 2015 Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment
- ISO 80601-2-74: 2017 Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- ISO 80601-2-79: 2018 Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device	Predicate Device K153061	Secondary Predicate Device K201620	Remark
Product Code	MNS	MNS	BZD	Same
Regulation Number	21 CFR 868.5895	21 CFR 868.5895	21 CFR 868.5905	Same
Indication for Use	The BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with Obstructive Sleep Apnea (OSA) or Respiratory Insufficiency. The integrated humidifier is indicated for the humidification and warming of air from the flow generator device. The device is intended for adult patients weighing more than 66lbs (30 kg) by prescription. The device is intended for single patient use in the home environment and multi-patient re-use in the hospital/institutional environment.	The Juno VPAP ST-A is indicated to provide noninvasive ventilation for patients weighing more than 30lbs (13 kg) with respiratory insufficiency or obstructive sleep apnoea (OSA). The iVAPS mode is indicated for patients weighing more than 66lbs (30 kg). The Juno VPAP ST-A is intended for home and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.	The luna® G3 BPAP 25A is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult obstructive Sleep Apnea (OSA). The integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single-patient use by prescription in the home or hospital/institutional environment on adult patients. It is to be used on patients ＞66lbs/30kg for whom CPAP therapy has been prescribed. The system can deliver bi-level therapy or auto bi-level therapy.	Analysis 1
Environment of Use	Hospital/Home	Hospital/Home	Hospital/Home	Same
Supplemental oxygen	Yes	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same

Single Use	Reuse	Reuse	Reuse	Same
Prescription status	Prescription	Prescription	Prescription	Same
Alarm	Yes	Yes	No	Same
Humidifier				
Integrated	Yes	Yes	Yes	Same
Humidity Output	≥ 15 mg/L, as required by ISO80601-2-74	≥10 mg/L	≥ 15 mg/L, as required by ISO80601-2-74	Analysis 2
Humidifier Setting	1-5 (95 to 154.4°F/35 to 68°C)	1-8	1-5 (95 to 154.4°F/35 to 68°C)	Analysis 2
Delay	Yes	Yes	Yes	Same
Physical specification				
Dimensions	265 × 145×114 mm (with integrated humidifier)	153 mm x 172 mm x 86 mm	265 × 145×114 mm (with integrated humidifier)	Analysis 3
Weight	1.7kg (with integrated humidifier)	1.04kg	1.7kg (with integrated humidifier)	Analysis 3
AC Power	100-240V, 50/60Hz,	100~240V, 50~60Hz	100-240V, 50/60Hz	Same
Accessory				
Air filter	Yes	Yes	Yes	Same
Non-heated tubing	Yes	Yes	Yes	Same
Heated tubing	Yes	Yes	Yes	Same

Analysis 1-Indication for Use

The indication for use for the proposed device is not exactly same as the predicate device. Firstly, the intended patient weight for the proposed device does not include the population whose weight larger than 30lbs. The proposed device is just intended for the adult patients whose weight is larger than 66lbs and this population was also covered by predicate device. Therefore, it can be concluded that the intended population can be covered in the population range of predicate device. In addition, the proposed device is intended for single patient and multi-patients re-use, while the predicate device is intended for single patient re-use. However, whether single patient reuse or multi-patient reuse, the device shall be cleaned and disinfected prior to subsequent use, and the cleaning and disinfection method for the proposed device have been validated per FDA recognized standard, the test result is

acceptable.

Analysis 2- Humidity Output and humidifier setting

The humidity output and humidifier setting for the proposed device is different from predicate device, however, it is same as the secondary predicate device.

Analysis 3-Dimension and Weight

The dimension and weight for the proposed device is different from predicate device. The difference in weight and dimension will not affect the intended use and this difference will not raise any safety and effectiveness issue. In addition to the predicate device, a secondary predicate device was cited, it can be noted that the weight and dimension for the proposed device is same as the secondary predicate device.

Table 2 Performance and Safety Comparison

Item	Proposed Device	Predicate Device K153061	Secondary Predicate Device K201620	Remark
Modes Available	CPAP; S; T S/T; Auto CPAP Auto S	CPAP S T S/T PAC iVAPS	Auto CPAP Auto S S CPAP	Analysis 4
Pressure Range	CPAP: 4~20cmH_2O Auto CPAP: 4~20cmH_2O S: 4~25cmH_2O for G3B25VT, 4~30cmH_2O for G3 B30SV, G3 B30VT, G3 LAB; T: 4~25cmH_2O for G3B25VT,	CPAP: 4-20cmH_2O S, S/T, T: 3-30cmH_2O	For CPAP and Auto CPAP mode: 4.0~20.0 cmH_2O For Auto S and S mode: 4.0~25.0 cmH_2O	Analysis 5

	4~30cmH_2O for G3 B30SV, G3 B30VT,G3 LAB; S/T:4~25cmH_2O for G3B25VT, 4~30cmH_2O for G3 B30SV, G3 B30VT, G3 LAB; Auto S: 4~30cmH_2O			
Pressure regulation	±0.5 cmH_2O	±0.5 cmH_2O	±0.5 cmH_2O	Same
Automatic adjusting CPAP algorithm	Yes	No	Yes	Analysis 6
Ramp	0-60	User selected as “off” to 45minutes in 5 minutes increments Max ramp time set at clinician’s driscretion	0-60	Analysis 7
Expiratory Pressure Relief	Reslex® function Level 1-3	Yes	Reslex® function Level 1-3	Analysis 8
Cellular module	Yes	No	Yes	Analysis 9
iCode®	iCode, iCode QR, iCode QR + A feature that is intended to give access to compliance and therapy management information. The iCode consists of six separate codes displayed in the Patient Menu, each code is a sequence of numbers. The “iCode QR” and “iCode QR+” display	No	iCode, iCode QR, iCode QR + A feature that is intended to give access to compliance and therapy management information. The iCode consists of six separate codes displayed in the Patient Menu, each code is a sequence of numbers. The “iCode QR” and “iCode QR+” display two-dimensional codes.	Analysis 10

	two-dimensional codes.			
iCodeConnect® Software	Yes	No	Yes	Analysis 11
Transmit data	therapy data, therapy settings, upgrade device software	therapy data, therapy settings, upgrade device software	therapy data, therapy settings, upgrade device software	Same
Data transfer medium	SD card, Cellular module	SD card, Wireless	SD card, Cellular module	Analysis 12
Smart A	Yes	No	Yes	Same
Smart B	Yes	No	Yes	Same
Smart C	Yes	No	Yes	Same
Respiratory event detection function	Yes	Yes	Yes	Same
Biocompatibility				
Cytotoxicity	Comply with ISO 10993-5	Comply with ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-12 standards	Comply with ISO 10993-5	Same
Skin Irritation	Comply with ISO 10993-10		Comply with ISO 10993-10	
Sensitization	Comply with ISO 10993-10		Comply with ISO 10993-10	
Particulate matter	Comply with ISO 18562-2		Comply with ISO 18562-2	
Volatile organic compounds (VOCs)	Comply with ISO 18562-3		Comply with ISO 18562-3	
Leachables in condensate	Comply with ISO 18562-4		Comply with ISO 18562-4	
Electrical Safety	Comply with IEC 60601-1-8: 2012; AAMI/ANSI ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R) 2012 And A2:2010/(R) 2012; IEC 60601-1-11: 2011 ISO 80601-2-70:	Comply with IEC 60601-1:2005+AMD1: 2012 IEC 60601-1-8: 2006 IEC 60601-1-11:2010	Comply with IEC 60601-1-8: 2012; AAMI/ANSI ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R) 2012 And A2:2010/(R) 2012; IEC 60601-1-11: 2011 ISO 80601-2-70:	Same

	ISO 80601-2-74		ISO 80601-2-74	
EMC	IEC 60601-1-2: 2014	IEC 60601-1-2:2014	IEC 60601-1-2:2014	Same

Analysis 4-Working Mode

The working mode for the proposed device is not same as the predicate device. The CPAP, S, T and S/T mode can be covered by the predicate device. The working mode Auto CPAP and Auto S were not covered by the predicate device. These modes are similar, but the performance of these modes were assessed against the secondary predicate device.

Analysis 5-Pressure Range

The pressure range for the proposed CPAP, S, T, S/T mode can be covered by the predicate device. The working mode Auto CPAP and Auto S were not covered by the predicate device. Based on the discussion in analysis 4, these two additional working modes were compared to the secondary predicate device. The pressure range for proposed Auto CPAP and Auto S is larger than the secondary predicate device, this difference was caused by the proposed device was available in a series model and the largest pressure range model exceed the range of secondary predicate device. Although the largest pressure range for Auto CPAP and Auto S exceed the pressure range of secondary predicate device, but it does not exceed the pressure range of predicate device.

Analysis 6-Automatic Adjusting CPAP Algorithm

The automatic adjusting CPAP algorithm is not contained by the predicate device. This difference was caused by the working mode, since the predicate device does not have the Auto working mode. Therefore, the predicate device does not have automatic adjusting function. However, in addition to the predicate device, a secondary predicate device was cited to compare some technology characteristics which were not covered by the predicate device, it can be noted that this function can be covered by the secondary predicate device.

Analysis 7-Ramp

The ramp function for proposed device is not exactly same as the predicate device. However, in addition to the predicate device, a secondary predicate device was cited to compare some technology characteristics which were not covered by the predicate device, it can be noted that this function is same as

the secondary predicate device.

Analysis 8-Expiratory Pressure Relief

The relief function for proposed device is not exactly same as the predicate device. However, in addition to the predicate device, a secondary predicate device was cited to compare some technology characteristics which were not covered by the predicate device, it can be noted that this function is same as the secondary predicate device.

Analysis 9-Celluar Module

The cellular module is not contained by the predicate device. This module is used for the data transfer. However, in addition to the predicate device, a secondary predicate device was cited to compare some technology characteristics which were not covered by the predicate device, it can be noted that the cellular module is same as the secondary predicate device.

Analysis 10-iCode

The iCode function is not contained by the predicate device. However, in addition to the predicate device, a secondary predicate device was cited to compare some technology characteristics which were not covered by the predicate device, it can be noted that this function is same as the secondary predicate device.

Analysis 11-iCodeConnection Software

The iCode connection software is not contained by the predicate device. However, in addition to the predicate device, a secondary predicate device was cited to compare some technology characteristics which were not covered by the predicate device, it can be noted that this connection software is same as the secondary predicate device.

Analysis 12-Data Transfer Medium

The data transfer medium for the proposed device is not exactly same as predicate device, the SD card medium can be covered by the predicate device. Cellular module is not included by the predicate device. However, in addition to the predicate device, a secondary predicate device was cited to compare some technology characteristics which were not covered by the predicate device, it can be noted that cellular module is covered by the secondary predicate device. In addition, the electrical safety and EMC test has been conducted on the proposed device. The cellular module can work normally in interference environment.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.