March 9, 2022

BMC Medical Co., Ltd.
Amy Wang
RA
Room 901, Building 1, No. 28 Pingguoyuan Road
Beijing, Shijingshan 100041
China

Re: K211155
Trade/Device Name: Auto CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: February 7, 2022
Received: February 7, 2022

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 (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,

Rachana Visaria, Ph.D.
Assistant 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)*
K211155

Device Name
Auto CPAP System

Indications for Use *(Describe)*
Auto CPAP System is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only, either in the hospital or at home.
Auto CPAP System is for prescription use only. It is a travel CPAP device intended for single-patient use.

LightTrip App is a mobile application for patients to remotely operate BMC Mini serial devices, and transmit, store and display usage and treatment information. It can also receive parameters and device firmware upgrade data from the cloud, and then transmit these data to the device. The LightTrip app also allows healthcare professionals to remotely configure compatible OSA therapy devices. LightTrip App is for prescription use only.

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.

510(k) Summary

Device Trade Name	Auto CPAP System
Model	M1 Mini
Common/Usual Name	Auto CPAP System
Date Prepared	March 8, 2022
Sponsor Identification	BMC Medical Co., Ltd. Room 901, Building 1, No.28 Pingguoyuan Road, Shijingshan, Beijing 100041, CHINA
Submission Correspondent	Amy Wang BMC Medical Co., Ltd. Room 901, Building 1, No.28 Pingguoyuan Road, Shijingshan, Beijing 100041, CHINA
Phone	86-18701556244
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Establishment Registration #	3008566132
	BMC Medical Co., Ltd. Room 901, Building 1, No.28 Pingguoyuan Road, Shijingshan, Beijing 100041, CHINA
Classification	Class II Device (21 CFR 868.5905)
Classification Name	Noncontinuous ventilator
Classification Panel	Medical Device
Products Code	BZD
Medical Specialties	Anesthesiology
Predicate Device(s)	Luna CPAP and Auto CPAP System (K153387)
	Menai System (K160836)

Reason for Submission:	New Device
Indications for Use	Auto CPAP System is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only, either in the hospital or at home. Auto CPAP System is for prescription use only. It is a travel CPAP device intended for single-patient use. LightTrip App is a mobile application for patients to remotely operate BMC Mini serial devices, and transmit, store and display usage and treatment information. It can also receive parameters and device firmware upgrade data from the cloud, and then transmit these data to the device. The LightTrip app also allows healthcare professionals to remotely configure compatible OSA therapy devices. LightTrip App is for prescription use only.
Device Description	Auto CPAP System is a microprocessor controlled, blower-based system that generates continuous positive airway pressure (CPAP) to support treatment of obstructive sleep apnea. The system provides fixed or auto-adjust pressure from 4 to 20 cmH_2O above the ambient atmospheric pressure to a patient's oral/nasal airway. The Auto CPAP System is designed and developed on the basis of the predicate device Luna CPAP and Auto CPAP System (K153387). The parameters and algorithms of the two devices, such as the treatment mode (CPAP and AutoCPAP), the pressure range (4 to 20 cm H2O), and the Respiratory Event Detection, are consistent. Compared with the predicate device, the subject device does not include a humidifier and an LCD screen. The parameters of subject device are displayed and set via the LightTrip App.

Substantial Equivalence:

The subject and predicate devices have the following similarities:

- Same Indications for Use
- Similar operating principle
- Similar technologies

Auto CPAP System retains similar functionality and performance features of the primary predicate device Luna CPAP and Auto CPAP System (K153387). It utilizes the same algorithm as the primary predicate device Luna CPAP and Auto CPAP System (K153387) for respiratory event detection and therapy for sleep disordered breathing events. The subject device and the primary

predicate device share the similar intended use, similar operating principal, and are manufactured and packaged with similar processes.

Compared with the primary predicate device, the subject device makes the following main modifications:

- By removing the humidifier, the subject device is provided in a portable smaller footprint than the predicate for user convenience, especially for using on an aircraft or in travel. Choosing a mask with a humidifier component can improve the moisture level in the breathing air and offer relief from possible dryness.

- The subject device includes a Bluetooth module, which enables the device to be connected with the LightTrip App on the smartphone.

- LightTrip App is a mobile application of Auto CPAP System. The patient and the health care professional can set parameters of the device via this application. Patients can set the comfort settings, turn the device on and off using the LightTrip App. However, only health care professional is able to remotely change the prescription settings. The device can upload the running data to LightTrip App where they can be displayed, stored and uploaded to the cloud platform. LightTrip App can also obtain the remote parameter setting of the cloud platform and realize the on-line firmware upgrade of the device.

The substantial equivalence comparison is provided below.

	Subject Device	Primary Predicate Device	Reference Device	
	Auto CPAP System (K211155)	**Luna® CPAP and Auto CPAP System (K153387)**	**Menai System (K160836)**	**Comparison**
Classification				
Device Classification	Class II Device	Class II Device	Class II Device	Identical to primary predicate
Product Code	BZD	BZD	BZD, MNR	Identical to primary predicate
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology	Identical to primary predicate
Regulation Number	21 CFR 868.5905	21 CFR 868.5905	21 CFR 868.5905 21 CFR 868.2375	Identical to primary predicate
Regulation Name	Noncontinuous ventilator	Noncontinuous ventilator	Noncontinuous ventilator	Identical to primary predicate
Sterile	Non-sterile	Non-sterile	Non-sterile	Identical to primary predicate
Intended Use and Indications for Use				

	Subject Device	Primary Predicate Device	Reference Device	
	Auto CPAP System (K211155)	**Luna® CPAP and Auto CPAP System (K153387)**	**Menai System (K160836)**	**Comparison**
Intended Use of the Device	Auto CPAP System is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only, either in the hospital or at home. Auto CPAP System is for prescription use only. It is a travel CPAP device intended for single-patient use.	The Luna CPAP and Auto CPAP System are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated heated humidifier is indicated for the humidification and warming of air from the flow generator. These devices are intended for single patient use by prescription in the home or hospital / institutional environment on adult patients.	The Menai self-adjusting system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg). It is intended for home and hospital use.	Similar to primary predicate.
Intended Use of the Software Application	LightTrip App is a mobile application for patients to remotely operate BMC Mini serial devices, and transmit, store and display usage and treatment information. It can also receive parameters and device firmware upgrade data from the cloud, and then transmit these data to the device. The LightTrip app also allows healthcare professionals to remotely configure compatible OSA therapy devices. LightTrip App is for prescription use only.	N/A	Monte Carlo is a mobile application for patients to remotely operate a prescribed compatible ResMed machine and transfer, analyze and display usage and therapeutic information. Monte Carlo also allows healthcare professionals to remotely configure compatible OSA therapy devices.	Similar to the secondary predicate.

	Subject Device	Primary Predicate Device	Secondary Predicate Device	
	Auto CPAP System (K211155)	**Luna® CPAP and Auto CPAP System (K153387)**	**Menai System (K160836)**	**Comparison**
Pressure Delivery				
Therapy Delivered	CPAP, AutoCPAP	CPAP, AutoCPAP	CPAP， AutoSet， AutoSet for Her (AfH)	Identical to primary predicate
Pressure Range	4 to 20 cm H_2O (in 0.5 cm H_2O increments), ≤30 cm H_2O under single fault conditions	4 to 20 cm H_2O (in 0.5 cm H_2O increments), ≤ 30 cm H_2O under single fault conditions	• 4-20 cm H_2O (CPAP Mode) • 4-20 cm H_2O (AutoSet Mode) • 4-20 cm H_2O (AutoSet AfH Mode) • EPR +3 cm H_2O (all modes)	Identical to primary predicate
Pressure Display Accuracy (hPa)	±(0.5 hPa＋4%)	±(0.5 hPa＋4%)	±0.5 hPa	Identical to primary predicate
Algorithm				
Automatic adjusting CPAP algorithm	Yes	Yes	Yes	Identical to primary predicate
Ramp	Yes, the ramp time ranges from 0 to 60 minutes	Yes, the ramp time ranges from 0 to 60 minutes	Yes, user selected as “Off” to 45 minutes in 5 minute increments	Identical to primary predicate
Expiratory Pressure Relief	Yes, Reslex® function Level 1-3	Yes, Reslex® function Level 1-3	Yes, EPR function	Identical to primary predicate
Respiratory Event Detection	OSA detection Hypopnea detection Snore detection	OSA detection Hypopnea detection Snore detection	OSA detection Hypopnea detection Snore detection	Identical to primary predicate
Physical Characteristics				

	Subject Device	Primary Predicate Device	Secondary Predicate Device	
	Auto CPAP System (K211155)	**Luna® CPAP and Auto CPAP System (K153387)**	**Menai System (K160836)**	**Comparison**
IEC 60601 Classification	Class Ⅱ, Type BF	Class Ⅱ, Type BF	Class Ⅱ, Type BF	Identical to primary predicate
Degree of Protection Against Water Ingress	IP22	IP22	IP22	Identical to primary predicate
Sound Pressure Level	< 30 dB, when the device is working at the pressure of 10 hPa.	< 30 dB, when the device is working at the pressure of 10 hPa.	Air tubing connected to AirMini F20 connector with mask: 19 dBA with uncertainty of 3 dBA; Air tubing connected to AirMini N20 or P10 connectors with mask: 15 dBA with uncertainty of 3 dBA	Identical to primary predicate
Air Filter	Yes	Yes	Yes	Identical to primary predicate
Non-heated Tubing	Yes	Yes	Yes	Identical to primary predicate
Humidifier	No	Yes	No	Identical to secondary predicate device. Choosing the appropriate mask with humidification component can improve the moisture level in the breathing air and offer relief from possible dryness.

	Subject Device	Primary Predicate Device	Secondary Predicate Device	
	Auto CPAP System (K211155)	**Luna® CPAP and Auto CPAP System (K153387)**	**Menai System (K160836)**	**Comparison**
Data Reporting				
Wireless Function	Bluetooth	N/A	Bluetooth	Identical to secondary predicate device
Parameters Transferred by the Mobile App	Usage and treatment data	N/A	Usage and therapeutic data	Identical to secondary predicate device

Performance Data：

The following performance data were used in support of the substantial equivalence determination.

Bench Testing:

To demonstrate that the performance of the subject device is substantially equivalent to the predicate device, the following bench testing were conducted according to ISO 80601-2-70:2015:

- Maximum flow rate testing
- Static pressure testing
- Dynamic pressure testing
- Sound pressure level testing
- Display accuracy testing

Biocompatibility Assessment:

Evaluation and testing of biocompatibility were conducted in accordance with the following standards and guidance documents:

• ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

• FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" June 16, 2016

• ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

• ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

• ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process

• ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter

• ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)

• ISO 18562-4:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate

Electrical Safety and Electromagnetic Compatibility:

Electrical safety and EMC testing were conducted on the subject device Auto CPAP System. The system complies with the following standards for electrical safety and EMC:

• AAMI/ANSI ES 60601-1:2005/(R) 2012 And A1:2012. Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance

• 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

• 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

• ISO 80601-2-70:2015 Medical electrical equipment Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment

Software Verification and Validation:

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff:

• "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

• "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"

• "Guidance-Radio Frequency Wireless Technology in Medical Devices"

Mechanical Testing:

Mechanical Shock Test, Sine Vibration, etc. were conducted on the subject device. Results of the tests show that there is no new safety or effectiveness question.

Conclusion

Auto CPAP System has similar intended use as the predicate device. The 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.