March 25, 2022

3B Medical, Inc.
Yasser Estafanous
Chief Quality & Regulatory Officer
203 Avenue A NW, Suite 300
Winter Haven, Florida 33881

Re: K212263
Trade/Device Name: Luna G3 BPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: August 11, 2021
Received: February 17, 2022

Dear Yasser Estafanous:

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
K212263

Device Name
Luna® G3 BPAP System

Indications for Use *(Describe)*
The Luna® G3 BPAP System 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 > 66 lbs / 30 kg for whom CPAP therapy has been prescribed.

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

Device Trade Name	Luna® G3 BPAP System
Model	LG3800-25VT, LG3800-30VT
Common/Usual Name	BPAP System
Date Prepared	May March 23, 2022
Sponsor Identification	3B Medical, Inc. 203 Avenue A NW, Suite 300, Winter Haven, FL 33881
Submission Correspondent	Yasser Estafanous 3B Medical, Inc. 203 Avenue A NW, Suite 300, Winter Haven, FL 33881
Phone	863-226-6285
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Email	yestafanous@3bproducts.com
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	Luna G3 BPAP 25A (K201620)
Reference Device	Juno VPAP ST-A (K153061)

Reason for Submission: Device Modification

Intended Use: The Luna® G3 BPAP System 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 > 66 lbs / 30 kg for whom CPAP therapy has been prescribed.

Device Description: The Luna® G3 BPAP system is a microprocessor controlled, blower-based system that generates positive airway pressure to support treatment of obstructive sleep apnea. Its hardware design is identical to the previously cleared Luna® G3 BPAP 25A (K201620). The subject device includes two models, with different pressure ranges. They both have four therapy modes, which are CPAP, Spontaneous (S), Timed (T) and Spontaneous/Timed (S/T). The pressure ranges and modes are listed as follows:

Product Name	**Model**	**Pressure Range**	**Work Modes**
Luna® G3 BPAP system	LG3800-25VT	4-25 cmH_2O	CPAP, S, T, S/T
	LG3800-30VT	4-30 cmH_2O	CPAP, S, T, S/T

Comparison of Technological Characteristics with the Predicate Device:

The Luna® G3 BPAP System uses the same hardware and basic algorithm as the predicate Luna® G3 BPAP 25A (K201620). The subject device and the predicate share the same intended use, same operating principle, same materials, and are manufactured and packaged with the same processes. The basic functionality and performance characteristics of the subject device are the same as the predicate. The only differences of the subject device with the predicate are as follows:

- Apart from the CPAP and S modes that are identical to the predicate, the subject device LG3800-25VT and LG3800-30VT have two new work modes: T mode and S/T mode.

- The subject device LG3800-30VT provides a wider pressure range of 4-30 cmH_2O, while LG3800-25VT provides the same pressure range of 4-25cmH_2O with the predicate.

The reference device Juno VPAP ST-A (K153061) comprises the working modes of T and S/T, and its working pressure ranges from 3-30cmH_2O. The relevant functionality and performance characteristics of the subject device Luna® G3 BPAP System are the same as those of the reference device. Testing and comparison were conducted on the subject device and the reference device. They are substantially equivalent on the above features.

The substantial equivalence comparison is provided as below.

	Subject Device	Predicate Device	Reference Device	Comparison
	Luna® G3 BPAP System (K212263)	**Luna® G3 BPAP 25A (K201620)**	**Juno VPAP ST-A (K153061)**	
Classification				
Device Classification	Class II Device	Class II Device	Class II Device	Identical to predicate
Product Code	BZD	BZD	MNS	Identical to predicate
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology	Identical to predicate
Regulation Number	21 CFR 868.5905	21 CFR 868.5905	21 CFR 868.5895	Identical to predicate
Intended Use and Indications for Use				

	Subject Device	Predicate Device	Reference Device	Comparison
	Luna® G3 BPAP System (K212263)	**Luna® G3 BPAP 25A (K201620)**	**Juno VPAP ST-A (K153061)**	
Indications For Use	The Luna® G3 BPAP System 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 > 66 lbs / 30 kg for whom CPAP therapy has been prescribed.	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.	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.	Identical to predicate
Pressure Delivery				
Therapy Delivered	CPAP, S, T, S/T	CPAP, AutoCPAP, S, Auto S	CPAP, S, T, S/T, PAC, iVAPS	CPAP and S modes are identical to predicate. T and S/T modes are identical to reference device.

	Subject Device	Predicate Device	Reference Device	Comparison
	Luna® G3 BPAP System (K212263)	**Luna® G3 BPAP 25A (K201620)**	**Juno VPAP ST-A (K153061)**	
Pressure Range	CPAP mode: 4−20 cmH_2O S, T, S/T mode: 4-25 cmH_2O for LG3800-25VT, 4-30 cmH_2O for LG3800-30VT	CPAP mode: 4−20cmH_2O S mode: 4−25cmH_2O	CPAP mode: 4−20 cmH_2O S, T, S/T mode: 3-30 cmH_2O	For LG3800-25VT, the pressure range is identical to the predicate. For LG3800-30VT, the pressure range of CPAP mode is identical to the predicate, while that of S, T, S/T mode is similar to the reference device.
Pressure Display Accuracy (hPa)	±(0.8cmH_2O+4%)	±(0.8cmH_2O+4%)	±(0.5 cmH_2O＋4%)	Identical to predicate
Humidifier				
Integrated	Yes	Yes	Yes	Identical to predicate
Humidifier Settings	1-5 (95 to 154.4°F/35 to 68°C)	1-5 (95 to 154.4°F/35 to 68°C)	1-8	Identical to predicate
Physical Characteristics				
Dimensions	265 × 145×114 mm (with integrated humidifier)	265 × 145×114 mm (with integrated humidifier)	255 mm x 150 mm x 116 mm (with integrated humidifier)	Identical to predicate
Weight	1.7kg (with integrated humidifier)	1.7kg (with integrated humidifier)	1.336kg (with integrated humidifier)	Identical to predicate
AC Power Consumption	100-240V, 50/60Hz, 2.0A	100-240V, 50/60Hz, 2.0A	100-240 V AC, 50-60 Hz, 1.0-1.5A	Identical to predicate

	Subject Device	Predicate Device	Reference Device	Comparison
	Luna® G3 BPAP System (K212263)	**Luna® G3 BPAP 25A (K201620)**	**Juno VPAP ST-A (K153061)**	
IEC 60601 Classification	Class Ⅱ, Type BF	Class Ⅱ, Type BF	Class Ⅱ, Type BF	Identical to predicate
Degree of Protection Against Water Ingress	IP22	IP22	IP22	Identical to predicate
Sound Pressure Level	< 26 dB, when the device is working at the pressure of 10 cmH_2O.	< 26 dB, when the device is working at the pressure of 10 cmH_2O.	< 27 dB, when the device is working at the pressure of 10 cmH_2O.	Identical to predicate
Air Filter	Available	Available	Available	Identical to predicate
Non-heated Tubing	Available Model: L1	Available Model: L1	Available	Identical to predicate
Heated Tubing	Available Model: LH1	Available Model: LH1	Available	Identical to predicate
Cellular Module	Available 4G Module	Available 4G Module	Available	Identical to predicate
Operating Conditions				
Atmospheric Pressure	760 to 1060 cmH2O	760 to 1060 cmH2O	738 to 1013 cmH2O	Identical to predicate
Operating Altitude	0 to 8,000 ft	0 to 8,000 ft	0 to 8,500 ft	Identical to predicate

Operating Temperature	5°C to 35°C (41˚F to 95˚F)	5°C to 35°C (41˚F to 95˚F)	5°C to 35°C (41˚F to 95˚F)	Identical to predicate
Operating Humidity	15% to 93% non-condensing	15% to 93% non-condensing	10 to 95% relative humidity, non-condensing	Identical to predicate
Shipping and Storage Conditions				
Shipping /Storage Temperature	-25°C to 70°C	-25°C to 70°C	-20°C to +60°C	Identical to predicate
Shipping /Storage Humidity	15% to 93% non-condensing	15% to 93% non-condensing	5% to 95% relative humidity, non-condensing	Identical to predicate
Data Reporting				
iCode®	Available	Available	NA	Identical to predicate
iCodeConnect® Software	Available	Available	NA	Identical to predicate
Reprocessing				
Single-patient Use	Yes	Yes	Single patient use in the home environment and re-use in a hospital/institutional environment	Identical to predicate
Sterilization/ Reuse	Not provided sterile. Reusable with cleaning instructions	Not provided sterile. Reusable with cleaning instructions	When the device is used for multiple patients, the cleanable parts should be cleaned and disinfected between each patient use. If the cleanable parts are being used for a single user, refer	Identical to predicate

			to the cleaning instructions in the User Guide.	

Non-Clinical Performance Testing:

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

- **Biocompatibility Evaluation:**

The subject device is categorized as permanent contact duration (>30 days) including dry and humidified gas pathways. As the subject device has no changes in material, manufacturing process, and hardware from the predicate (K201620, same manufacturer/sponsor), the following Biocompatibility testing from the predicate submission were leveraged to support substantial equivalence:

• 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

Additionally, to verify the biocompatibility of the subject device during the whole life cycle, the following testing was conducted post accelerated aging. The accelerated aging test was used to simulate the use of the subject device under worst case conditions over the whole life cycle.

- ISO18562-2:2017 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)

- **Electromagnetic Compatibility:**

EMC Testing was conducted on the subject device in accordance with the following standard:

• IEC 60601-1-2:2014 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – requirements and tests

- **Performance Testing:**

Testing was conducted on the subject device in accordance with the following standards for performance evaluation:

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

The following performance comparison testing was conducted on the subject device as well as the predicate and reference devices, to support the substantial equivalence:

- Maximum flow rate
- Static pressure
- Dynamic pressure
- Sound pressure level
- Rise time
- Display accuracy
- Pressure conversion

- **Software Verification and Validation:**

Software verification and validation 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"

- **Other Non-clinical Performance Testing**
  The subject device has no changes in material, manufacturing process, and hardware from the predicate (K201620, same manufacturer/sponsor). Therefore, the following testing from the predicate submission were leveraged to support substantial equivalence.

  - Reprocessing
  - Electrical safety
  - Mechanical safety
  - Cybersecurity

Conclusion

The subject device and the predicate device have the same intended use. They are identical in terms of structure, material and basic algorithm. Risk analysis, EMC testing, and performance comparison testing demonstrated that the subject device is substantially equivalent to the predicate device.