DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 22, 2015

3B™ Medical, Inc
Mr. Alex Lucio
Vice President
21301 Highway 27 N.
Lake Wales, FL 33859

Re: K141770
Trade/Device Name: Luna CPAP and Auto-CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 6, 2015
Received: March 23, 2015

Dear Mr. Lucio:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
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Office of Device Evaluation
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Enclosure

Indications for Use

510(k) Number: K141770
Luna CPAP and Auto CPAP System

Indications for Use:

The 3B Luna CPAP and Auto CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated 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.

Prescription Use: _X_ AND/OR Over-The-Counter Use: ___
(Part 21 CFR 801 Subpar D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Device Trade Name	Luna CPAP and Auto-CPAP Systems with Integrated Heated Humidifier
Common/Usual Name	CPAP System, Auto-CPAP system
Date Prepared	April 16, 2015
Sponsor Identification	3B Medical, Inc. 21301 Highway 27 N. Lake Wales, FL 33859
Phone	863-226-6285
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Establishment Registration #	3008566132
	BMC Medical CO., LTD 5/f Main Building No.19 Gucheng Street West, Shinjingshan Beijing, CHINA 100043
Classification	Class II Device
Classification Name	Non-continuous ventilator
Classification Panel	Medical Device
Classification Reference	21 CFR 878.5905
Products Code	BZD
Medical Specialties	Anesthesiology
Predicate Device(s)	RESmart® CPAP and Auto-CPAP Systems (K132967)
Reason for Submission:	Device Modification
Intended Use	The 3B Luna CPAP and Auto CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated 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.
Device Description	The Luna CPAP and Auto CPAP System is a microprocessor-controlled, blower-based system that generates positive airway pressure from 4 to 20 cm H20. The device is intended for

use with a patient interface (mask). The device has been modified to include a color LCD, menu driven user interface, and a redesigned enclosure. The electrical circuit was redesigned to incorporate the color LCD. The basic functionality and performance characteristics of the Luna CPAP and Auto CPAP are unchanged from the predicate device RESmart CPAP and Auto CPAP (K132967).

Non-Clinical Testing

Extensive non-clinical testing was conducted according to ISO 17510-1:2007, Sleep Apnea Breathing Therapy-Part I: Sleep Apnea Breathing Therapy Equipment. Side by side Performance Bench Testing demonstrated substantial equivalence with the predicated device.

Biocompatibility

The materials in the predicate device are identical and manufactured with the same manufacturing processes as the predicate device K132967; hence biocompatibility testing is not required.

Materials used in the construction of components that contact the heated humidified gas pathway are classified as permanent "external communicating devices" (with tissue/bone/dentin).

The appropriate biological tests conducted and passed for these components, in accordance with FDA guidance #G95-1- were performed in K132967:

- ISO 10993-3 Genotoxicity,
- ISO 10993-5 Cytotoxicity
- ISO 10993-6 Implantation and
- ISO 10993-10 Sensitization and Irritation

Testing for particulate matter and volatiles also demonstrated compliance to EPA requirements in K132967.

The Luna CPAP has been tested to appropriate standards and other applicable requirements. The Luna CPAP with integrated heated humidifier was designed and tested according to:

- IEC 60101-1:2005, Medical electrical equipment – Part 1: General Requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-2:2007, medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

The proposed and predicate devices have identical materials, indications for use, and operating principles. Testing and validation of component part upgrades establish substantial equivalence between predicate and proposed devices.

Substantial Equivalence

The proposed Luna CPAP and Auto CPAP System remain substantially equivalent to the RESmart II CPAP and AutoCPAP/Luna CPAP and AutoCPAP System (K132967) in that they have the same intended use, same operating principle, technology, identical materials, and manufacturing process. Designed validation and verification

tests were performed on the Luna CPAP and Auto-CPAP System because of the risk analysis and product requirements.

Comparative Summary of Technological Characteristics

Features/ Function	Proposed Device（K141770）	Predicate Device（K132967）
	Luna CPAP and Auto CPAP Systems	**RESmart CPAP/APAP** (Private labeled as 3B CPAP/APAP)
Therapy Delivered	CPAP, Auto CPAP	CPAP, Auto CPAP
Operation Temperature	5 to 35° C (41 to	5 to 30° C (41 to 86 F)
Storage/Transport Temperature	-25 to 70° C	-20 to 55° C
Humidity	15% to 93% Non-condensing	≤ 80% Non-condensing
Atmospheric Pressure	76 to 106 kPa	86 to 106 kPa
Standards Compliance	IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment IEC60601-1-11 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC 60601-1-2 Electromagnetic Compatibility	IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment IEC 60601-1-2 Electromagnetic Compatibility ISO 8185 General Requirements for Humidification Systems
Mode of Operation	Continuous	Continuous
AC Power Consumption	100-240VAC, 50/60Hz, 2.0A max	100-240VAC, 50/60Hz, 1.0A max
Software	Microprocessor controlled	Microprocessor controlled

System Contents	Air blower, pressure-flow monitoring, pressure controlling, user interface, heated humidifier, power cord, carrying case, user manual.	Air blower, pressure-flow monitoring, pressure controlling, user interface, heated humidifier, power cord, carrying case, user manual.
Type of Protection Against Electric Shock	Class II Equipment	Class II Equipment
Degree of Protection Against Electric Shock	Type BF Vertical Applied Part	Type BF Vertical Applied Part
Degree of Protection Against Ingress of Water	IP22	IPX1-Drip- Proof, Vertical
Pressure Range	4-20 cmH20 (in 0.5 cmH20 increments)	4-20 cmH20 (in 0.5 cmH2) increments)
Sound Pressure Level	<30 dB, when the device is working at the pressure of 10 cmH20	<30 dB, when the device is working at the pressure of 10 cmH2O.
Housing	flame retardant Engineering thermoplastic	flame retardant Engineering thermoplastic
Pressure Display Accuracy (cmH20)	± (0.5＋4%)	0.5
Ramp (minutes)	0-60	0-60
Mask off alert	Yes	Yes
Integrated Humidifier	Yes	Yes
Static and dynamic pressure accuracies	4 to 20 cmH20(±1 cmH20) Measured in accordance with preen 17510 @ 6.6, 13.2, & 20 cm H2O @ 500 ml with BPM set to 10, 15, & 20 BPM performed at 23° C (±2° C), 50% RH (±5%), and an atmospheric pressure of 101.5 kPa.	4 to 20 cmH20(±1 cmH20) Measured in accordance with prEN 17510 @ 6.6, 13.2, & 20 cm H2O @ 500 ml with BPM set to 10, 15, & 20 BPM performed at 23° C (±2° C), 50% RH (±5%), and an atmospheric pressure of 101.5 kPa.

Humidifier	Yes **Water Capacity:** 350 ml at recommended water level **Heater Settings:** 1 to 5 (95 to 167 °F) **Pressure Drop with Humidifier:** < 0.4 cmH20 at 60 LPM flow **Humidity Range:** ≥10mg/L	Yes **Water Capacity :**> 350 ml **Heater Settings:** 1 to 5 (104 to 149 °F) **Pressure Drop with Humidifier :**< 0.5 cmH20 at 60 LPM flow; **Humidity Range:** 10 to 40 mg H_2O/L

Conclusions

There have been no changes in the material composition, intended use, or operating principles. Performance bench testing and device validation and verification demonstrate that the proposed device is substantially equivalent to the predicate device.