DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 25, 2014

BMC Medical Co., Ltd.
Alex Lucio, Vice President
3B Medical, Inc.
21301 US Highway 27 N
Lake Wales, FL 33859

Re: K133769
Trade/Device Name: RESmart® BPAP 25A
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: Class II
Product Code: BZD
Dated: July 23, 2014
Received: July 25, 2014

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,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133769

Device Name
RESmart BPAP 25A

Indications for Use *(Describe)*
The 3B and BMC RESmart BPAP system is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA). The optional 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Trade Name	RESmart BPAP 25A
Common/ Usual Name	BPAP System
Date Prepared	19 November 2013
Sponsor Identification:	3B Medical, Inc. 21301 Highway 27 N. Lake Wales, FL 33859
Submission Correspondent	Alex Lucio Vice President 3B Medical, Inc. 21301 Highway 27 N. Lake Wales, FL 33859 T: (863)226-6285 ext. 101 F: (863)226-6284 alucio@3bproducts.com
Establishment Registration #	3008566132 BMC MEDICAL CO., LTD 5/f Main Building No. 19 Gucheng Street West, Shijingshan Beijing, CHINA 100043
Classification	Class II Device
Classification Panel	Anesthesiology
Classification Reference	21 CFR 868.5905
Product Code	BZD –Non-continuous Ventilator (Respirator)
Predicate Device(s)	Predicate Respironics BiPAP Auto (K050759) Predicate RESmart® Auto-CPAP (K131707)
Indications for Use	The 3B and BMC RESmart® BPAP system is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA). The optional 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/intuitional environment on adult patients. It is to be

	used on patients (>66lbs/30kg) for whom positive airway pressure therapy has been prescribed. The system can deliver bi-level therapy or auto bi-level therapy.
Device Description	The RESmart BPAP is a microprocessor controlled blower based bi-level positive pressure system that delivers two different positive pressure levels (IPAP/EPAP) from 4 to 25 cmH_2O. The dual pressure levels provide a more natural means of delivering pressure support therapy to the patient resulting in improved patient comfort. Two operation modes are being introduced, including the Auto Bi-Level mode and Spontaneous Bi-Level mode. Bi-Level therapy with automatically adjusting IPAP and EPAP levels is delivered in the Auto Bi-Level mode at the prescribed pressure range. The Spontaneous Bi-Level mode delivers fixed prescribed inspiratory and expiratory pressure. The BPAP device is intended for use with a patient circuit that is used to connect the device to the patient interface (mask).
Purpose of Submission	Modified design to the RESmart System software to achieve bi-level functionality in order to provide a bi-level device as an alternate device for patients who reject standard CPAP therapy.
Performance Testing	Extensive testing was conducted in accordance with ISO 17510-1:2007, Sleep Apnea Breathing Therapy-Part I: Sleep Apnea Breathing Therapy Equipment. Clinical Testing and Performance Contrast Testing demonstrated substantial equivalence with the predicate device in terms of max flow rate, static pressure, dynamic pressure, and sound pressure. The air quality testing determined the device is substantially equivalent to the predicate device. The device was tested according to IEC 60601-1 with the result that the device meets all requirements for electrical safety and electromagnetic compatibility and is otherwise substantially equivalent with the predicate device. Testing and validation of component part upgrades establish substantial equivalence between predicate and proposed devices.

Substantial Equivalence	The RESmart BPAP remains substantially equivalent to the predicate RESmart CPAP and Auto-CPAP System (K131707) in that they share the same intended use, operating principle, and manufacturing process. The RESmart BPAP remains substantially equivalent to the predicate Respironics BiPAP Auto (K050759) in that they share the same intended use, operating principle, and performance. Design modifications were made to the RESmart system software to achieve bi-level functionality to provide a bi-level device as an alternate device for patients who reject standard CPAP therapy. Design verification tests were performed on the RESmart BPAP to ensure product requirements and evaluate risk analysis. All tests were verified to meet the required acceptance criteria. The RESmart BPAP is mechanically identical to the RESmart CPAP/Auto-CPAP System. The modification to the software involves change to algorithm to produce dual pressure delivery of IPAP and EPAP substantially equivalent to the same function in the Respironics BiPAP Auto. In summary, the device described in this submission is substantially equivalent to the predicates.
Truthful & Accuracy	A certification of truthfulness and accuracy of the RESmart BPAP as described in this submission is provided in Section 9.
Conclusion	The 3B and BMC RESmart BPAP is substantially equivalent to the predicate devices already approved by the FDA.