K132967
DEC - 6 2013

510(k) Summary

Device Trade Name	RESmart CPAP and Auto CPAP nP1.5
Common/ Usual Name	CPAP System, Auto CPAP System
Date Prepared	1 July, 2013
Sponsor Identification	3B Medical, Inc. 21301 Highway 27 N. Lake Wales, FL 33859
Phone	863-226-6285
Fax	863-226-6284
Email	alucio@3bproducts.com
Submission Correspondent	Alex Lucio 3B Medical, Inc. 21301 Highway 27 N. Lake Wales, FL 33859
Phone	863-226-6285
Fax	863-226-6284
Email	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	Medical Device
Classification Reference	21 CFR 878.5905
Product Code	BZD- Non-continuous Ventilator (Respirator)
Medical Specialties	Anesthesiology
Predicate Device(s)	RESmart® CPAP and Auto CPAP System (K110629)

Intended Use	The 3B and BMC RESmart 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 device. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.
Device Description	The RESmart CPAP and Auto CPAP System is a microprocessor-controlled, blower-based system that generates positive airway pressure from 4 to 20 cm H2O. The device is intended for use with a patient circuit that is used to connect the device to the patient interface (mask). The RESmart CPAP and Auto CPAP device has been modified to include a smaller and quieter blower. The air circuit, embedded software, and controller board were upgraded to provide better performance. The basic functional and performance characteristic of the RESmart CPAP and Auto CPAP are unchanged from the predicate device RESmart CPAP and Auto CPAP (K110629).
Non-Clinical Testing	Extensive non-clinical testing was conducted in according with ISO 17510-1:2007, Sleep Apnea Breathing Therapy-Part I: Sleep Apnea Breathing Therapy Equipment. Performance Bench Testing demonstrated substantial equivalence with the predicate device. Testing and validation of component part upgrades establish substantial equivalence between predicate and proposed devices.
Substantial Equivalence	The RESmart® CPAP and Auto CPAP System (K110629) remain substantially equivalent to the proposed RESmart® CPAP and Auto CPAP System in that they have the same intended use, same operating principle, same technology, identical materials, and same manufacturing process. Design validation and verification tests were performed on the RESmart CPAP and Auto CPAP system because of the risk analysis and product requirements.

Truthful and Accuracy	A certification of truthfulness and accuracy of the proposed RESmart CPAP and Auto CPAP System as described in this submission is provided in Section 8.
Conclusions	There have been no changes in the material composition, intended use, or operating principles. Validation and verification, as well as performance bench testing, demonstrate that the proposed device is substantially equivalent to the predicate device.

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

December 6, 2013

3B Medical, Incorporated
Alex Lucio
Vice President
21301 Highway 27 N
Lake Wales, FL 33859

Re: K132967
Trade/Device Name: RESmart CPAP and Auto-CPAP nP1.5
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-continuous Ventilator (Respirator)
Regulatory Class: Class II
Product Code: BZD
Dated: November 4, 2013
Received: November 7, 2013

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.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K 132967

BMC RESmart® CPAP/Auto CPAP nP1.5

Indications for Use:

The 3B and BMC RESmart 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 device. 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 Subpart 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)

Anya C. Harry -S
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