510(k) Summary

Device Trade Name	RESmart CPAP and Auto CPAP
Common/ Usual Name	CPAP System, Auto CPAP System
Date Prepared	31 May, 2013
Sponsor Identification:	3B Medical, Inc. 21301 Highway 27 N. Lake Wales, FL 33859
Phone: Fax:	863-226-6285 863-226-6284
Submission Correspondent	Alex Lucio Vice President 3B Medical, Inc. 21301 Highway 27 N. Lake Wales, FL 33859 863-226-6285 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	Medical Device
Classification Reference	21 CFR 868.5905
Product Code	BZD –Non-continuous Ventilator (Respirator)
Medical Specialties	Anesthesiology
Predicate Device(s)	RESmart CPAP and Auto CPAP System (K110629)

AUG 2 2 2013

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.

Please see the Indications for Use Statement in Attachment 5.

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 porting the iCode software to a web-based application. The basic functional and performance characteristic of the RESmart CPAP and Auto CPAP is unchanged from the predicate device RESmart CPAP and Auto CPAP (K110629).

Purpose of the Modifications:

The purpose of this modification is to port the iCode feature, used to report compliance data for insurance reimbursement, to a web based program. There are no changes in logic, algorithm, or function. Rather the extent of the device modification is a simple change from a desktop environment to a web server based environment.

For those modifications involving a software change, all software has been verified and code reviewed using the methods provided in our internal procedures. The following paragraphs provide a summary of the modifications:

1. Modification is the porting of the iCode feature to a web based application, which is referred to as the "iCode Report Generator."

    - The purpose of the modification is to accommodate the needs of a fast changing marketplace, and is preferable

to most homecare providers because it is web based, requires no software installation, and may also be used to empower patients by allowing patients to review their sleep data. The entire scheme of iCode is based on reading the device LCD display and recording the character string displayed. There is no software that directly connects, interfaces, or otherwise interacts with the RESmart device. The device modification consists only of porting the feature to a web based version.

2. Modification for using iCode, for Andriod and iPhone devices, which is referred to as an application.

- The purpose of the modification was developed to allow users to access the iCode Report Generator using their smartphone. The smartphone application allow manual entry of the iCode string displayed on the RESmart LCD display on the user's cell phone. The smartphone app interfaces with iCode Report Generator and forwards the iCode string in the URL call. The application promps the user to take a photograph, point and click. Using optical character recognition, the character string is extracted from the photograph, and then the string is passed to the iCode Report Generator.

Non-clinical Testing	Non-clinical testing includes software verification and validation of the iCode Report Generator and iCode Smartphone application. See Software Requirement Specifications of iCode Report Generator, App. A; System Test Report of iCode Report Generator, App. B; Software Requirements Specification for 3B/BMC iCode Smartphone Applications, App. C; System Test Report of iCode Smartphone Application, App. D; and the Software Summary of iCode Report Generator, App.E.
Substantial Equivalence	The RESmart CPAP and Auto CPAP System remain substantially equivalent to the RESmart CPAP and Auto CPAP System (K110629) in that they have the same intended use, same

operating principle, and same manufacturing process. Design verification tests were performed on the RESmart CPAP and Auto CPAP system because of the risk analysis and product requirements. The modifications described within have been evaluated in terms of both safety and effectiveness. All tests were verified to meet the required acceptance criteria. In summary, the device described in this submission is substantially equivalent to the predicate device.

Truthful & Accuracy

A certification of truthfulness and accuracy of the RESmart CPAP and Auto CPAP System as described in this submission is provided in Attachment 8.

Conclusions

There have been no changes in:

- Intended use
- Operating principle
- Manufacturing process
- All other packaging labels and labeling (instructions for use, package insert, and operator's manual) for the device are unchanged from the previously cleared version.

Verification and validation activities were conducted based on risk analysis and demonstrated substantial equivalence to the predicate.

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

August 22, 2013

3B Medical, Incorporated
Mr. Alex Lucio
Vice President
21301 Highway 27 North
LAKE WALES FL 33859

Re: K131707
Trade/Device Name: BMC RESmart™ CPAP/Auto CPAP
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 18, 2013
Received: July 23, 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division 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: K131707

BMC RESmart™ CPAP/Auto CPAP

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/intuitional 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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K131707