APR 2 7 2012

SECTION 5.0
510(k) SUMMARY

This 510 (k) summary is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR §807.92.

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1 5.1 ADMINISTRATIVE INFORMATION

5.1.1 Sponsor Identification

3B Products, LLC
1142 N. Scenic Highway
Lake Wales, FL 33853

5.1.2 Submission Correspondent

Alex Lucio
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3B Products, LLC
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5.2 Date Prepared: February 26, 2011 **Date Revised:** April 26, 2012

5.3 Device Trade Names

BMC RESmart™ CPAP System (Private labeled in the USA as "3B CPAP System").
BMC RESmart™ Auto CPAP System (Private labeled in the USA as "3B Auto CPAP" ("APAP" System")
BMC Humidifier (Private labeled in the USA as "3B Humidifier")

5.4.1 Model Numbers

RESmart™

RESmart™ Auto

5.4.2 Common Name: CPAP System, Auto CPAP (or, "APAP") System

5.4.3 Classification Name: Ventilator, Non-Continuous (Respirator)

5.4.4 Regulation Numbers: 21 CFR 868.5905

5.4.5 Proposed Regulation Class: Class II

5.4.6 Device Product Code: BZD

5.4.7 **Medical Specialties:** Anesthesiology

5. DEVICE DESCRIPTION

The BMC RESmart™ CPAP System (Private labeled in the USA as the "3B CPAP System") and the BMC RESmart™ Auto CPAP System (Private labeled in the USA as the "3B Auto CPAP System") are microprocessor controlled, blower-based systems that generate positive airway pressures from 4-20 cm H_2O. The devices are intended for use with a patient circuit that is used to connect the device to the patient interface, i.e., the mask.

The CPAP and Auto CPAP devices consist of a blower, pressure/flow monitoring, pressure controlling, user interface and optional heated humidifier. The air blower consists of a DC brushless motor, turbofan, and shell. Fresh air is sucked in via an inlet due to the vacuum created by the air blower. The inlet foam filters dust and other floating particles. The filtered air is compressed to a certain pressure and blown out via an outlet. The outlet pressure is determined by the motor rate speed, which is controlled by the pressure control system.

The device has a real time pressure/flow monitoring system. Sensors monitor the outlet air pressure/flow, providing feedback, which is used to control the rate of speed of DC brushless motor, which regulates outlet air pressure in real time. The leakage of the mask and tubing will lead to a decrease of the outlet air pressure. This can be detected by the monitoring system and feedback allows the pressure controlling system to modify the rate speed of motor. In this way, the lost pressure caused by leakage will be compensated. When system is in standby, the pressure/flow change caused by respiratory via mask will also be detected by monitoring system and the automatically turning on of the function will be achieved. Pressure/flow changes caused by removal of the mask and/or tubing will also be detected, triggering the device alert and stopping the pressure output of the device.

Device control, setting and system status are displayed and achieved by user interface including buttons and LCD. The backlit LCD can display the system status and parameters. The buttons consist of start/stop, humidifier, ramp and +/- user buttons. User and medical equipment vendor service personnel can control and set the device via these buttons.

The two models bundled into this 510(k) submission (RESmart© CPAP and Auto CPAP) are mechanically identical. The difference in

functionality is determined by the software. In the standard CPAP model, the automated pressure regulation module of the software is disabled. The CPAP System provides only one level of pressure. In contrast the Auto CPAP provides varying levels of pressure that automatically adjusts, based on the patient's needs. The pressure required to overcome obstruction may vary, based upon body position, sleep stage, weight, neck size, congestion, or other factors. The Auto CPAP System will adjust the pressures throughout the night as the patient's pressure requirements change. The Auto CPAP System will maintain an optimal pressure, which, in most cases, will be lower that the pressure provided by the CPAP System.

No mask is included with the device, and the mask must be purchased separately. The integrated humidifier is optional. It also is packaged and sold separately. This humidifier moistens the air delivered by the CPAP and Auto CPAP Systems. It is used only on a single patient and must not be re-used on another person in order to avoid the risk of cross-infection.

The heated humidifier is used to increase the outlet air temperature and humidity. The humidifier is an optional component packaged and sold separately, but when added, is integrated by simple snap in place mechanism to the CPAP device. The humidifier consists of a heated platform and water chamber. The water is heated, which raises the temperature and humidity of the air in contact. The humidifier is controlled via infrared port and powered by the main device. The temperature sensors ensure the desired temperature and safety.

The RESmart CPAP and Auto CPAP devices are mechanically identical. The two devices operate on the same principles; utilize the exact same components and circuit, design, and manufacturing approach. The only difference consists of the software algorithm driving the fan controller board. A summary of the software algorithm is attached to the Appendix. The output treatment pressure of the CPAP device is set by the physician and fixed. By contrast, the pressure delivered in an Auto CPAP device is adjusted automatically in real time by the Auto CPAP system by tracking patient's respiration and airflow.

The RESmart CPAP and Auto CPAP, and integrated humidifier, complies with IEC 60601-1 and EN ISO 17510-1

5.5 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.

5.5 PREDICATE DEVICE

5.5.1 Predicate Device Names:

Respironics REMstar Auto CPAP (K012554)

Resmed S7 Elite and Autoset Spirit CPAP (K024191)

5.6 SUBSTANTIAL EQUIVALENCE

Both the RESmart CPAP and APAP devices have the following similarities to the previously cleared predicate devices:

- Same intended use
- Same operating principle
- Similar technologies
- Similar manufacturing process

The following substantial equivalence comparison chart compares the proposed and predicate devices:

5.7 SUMMARY OF PERFORMANCE TESTING

1. Functional testing was performed to confirm that the RESmart© CPAP and Auto-CPAP is capable of meeting its stated performance specifications. The device passed all tests.

2. Testing was performed to confirm that the RESmart© CPAP and Auto-CPAP complies with the standards set forth in IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment, IEC 60601-1-2 Electromagnetic Compatibility, and ISO 17510-1 Sleep Apnea Breathing Therapy Devices. The device passed all tests.

3. Testing of the humidifier was performed to insure that the integrated humidifier complies with the standards of ISO 8185:1998 General Requirements for Humidification Systems. The humidifier passed all tests.

4. Testing of the RESmart© CPAP and APAP outlet air was performed to insure that the device was not responsible for production or leaching of any volatile organic compounds, that the device outlet air contained no unacceptable levels of CO, CO2, or Ozone. Testing was also performed to insure that particulate matter of the output air was within the acceptance criteria defined under EPA TO-15. The device passed all tests.

5.8 SUMMARY OF CLINICAL TESTING

Clinical testing was conducted on 30 patients, with manual scoring by an expert masked to the performance of the device. The clinical trial results indicate that the proposed device was substantially equivalent to the predicate device REMstar Auto with regards to respiratory event detection, sensistity, and therapy delivery pressure.

5.9 CONCLUSION

Both the RESmart© CPAP and APAP devices are substantially equivalent to the predicate devices in terms of the basic principles of operation and technology, and achieve the same level of efficacy and the same degree of safety as the predicate

devices.

Device safety and conformity to consensus guidelines were thoroughly tested, and the results of all testing are submitted in the attached appendix. Performance testing and clinical testing establish that the device is substantially equivalent to the predicate devices, as summarized in the Substantial Equivalence Comparison Chart. (See also Section 12, infra. for a detailed discussion on the substantial equivalence of the proposed device with the identified predicates).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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3B Products, Incorporated
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JUL 23 2012

Re: K110629
Trade/Device Name: RESmart CPAP, RESmart Auto-CPAP, and RESmart Humidifier
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 18, 2012
Received: April 24, 2012

Dear Dr. Estrin:

This letter corrects our substantially equivalent letter of April 27, 2012.

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.

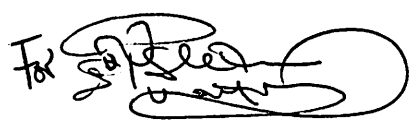
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
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Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

4.0 Indications for Use

510(k) Number: **K110629**

Device Name: RESmart™ CPAP and 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/institutional environment on adult patients.

Prescription Use ___X___

(Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____

(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

510(k) Number: K110629