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

September 8, 2016

3B Medical, Inc.
Alex Lucio
Vice President
799 Overlook Drive
Winter Haven, FL 33884

Re: K153387
Trade/Device Name: Luna® CPAP and Auto CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: July 28, 2016
Received: August 8, 2016

Dear Alex 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting 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)*
K153387

Device Name
Luna® CPAP and Auto CPAP System

Indications for Use *(Describe)*
The Luna® CPAP and Auto CPAP System are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated heated 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name	Luna® CPAP and Auto CPAP System
Common/Usual Name	CPAP System, Auto CPAP system
Date Prepared	September 8, 2016
Sponsor Identification	3B Medical, Inc. 799 Overlook Drive Winter Haven, FL 33884
Phone	863-226-6285
Fax	863-226-6284
Email	alucio@3bproducts.com
Submission Correspondent	Alex Lucio 3B Medical, Inc. 799 Overlook Drive Winter Haven, FL 33884
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 Name	Non-continuous ventilator
Classification Panel	Medical Device
Classification Reference	21 CFR 868.5905
Products Code	BZD
Medical Specialties	Anesthesiology
Predicate Device(s)	Luna® CPAP and Auto-CPAP Systems (K141770)
Reason for Submission:	Device Modification
Intended Use	The Luna® CPAP and Auto CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated heated 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 materials of water chamber of Luna® CPAP and Auto CPAP device were changed. The suppliers of Polycarbonate and silicone were changed. The basic functional and performance characteristics of the Luna® CPAP and Auto CPAP devices are unchanged from the predicate devices

(K141770).

Non-Clinical Testing

The modification of the device just changed in the materials, it did not refer to the modification of specification and performance. Biological tests about the change of materials have been done. Extensive non-clinical testing was conducted in according with ISO 10993 series standards.

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:

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

Series mechanical tests were also conducted to demonstrate the mechanical performance of the water chamber, including: drop test, leak test, and humidity performance test.

These test reports demonstrated substantial equivalence between the proposed and predicate devices.

Biocompatibility

The materials used in the chamber have been changed. In order to prove the new materials have no effect on safety, BMC conducted a series of tests on finished water chamber, including Intracutaneous Reactivity test, Ames test, In vitro Mammalian Cell Gene Mutation Test, Skin Sensitization Test, In vitro Mammalian

	Chromosome Aberration Test, In Vitro Cytotoxicity Test and Muscle Implantation Test.
Substantial Equivalence	The Luna® CPAP and Auto CPAP System (K141770) remain substantially equivalent to the proposed Luna® CPAP and Auto CPAP System in that they have the same intended use, same operating principle, same technology, and same manufacturing process. Biological tests were performed on the Luna® CPAP and Auto-CPAP System to prove the change of material does not affect the safety and effectiveness.
Conclusions	There have been no changes in the intended use, or operating principles. Biological testing demonstrated that the proposed device is substantially equivalent to the predicate device.