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

November 10, 2016

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

Re: K160127
Trade/Device Name: iCodeConnect
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: October 10, 2016
Received: October 12, 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)*
K160127

Device Name
iCodeConnect

Indications for Use *(Describe)*

iCodeConnect, in conjunction with a Luna CPAP or Auto-CPAP device, is intended for use in treating obstructive sleep apnea (OSA) on adult patients (>30 kg).

iCodeConnect is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been transmitted from the patient's Luna CPAP or Auto-CPAP therapy device located in the home to the clinician or healthcare professional. iCodeConnect also provides remote settings capabilities.

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.

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510(k) Summary

Device Trade Name	iCodeConnect
Common/Usual Name	Noncontinuous ventilator (IPPB)
Date Prepared	November 10, 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.19Gucheng Street West, Shijingshan,Beijing, CHINA 100043
Classification	Class II Device
Classification Name	Non-continuous ventilator
Classification Panel	Medical Device
Classification Reference	21 CFR 878.5905
Products Code	BZD
Medical Specialties	Anesthesiology
Predicate Device(s)	EasyCare Online (K093684)
Reason for Submission:	New Device
Intended Use	iCodeConnect, in conjunction with a Luna CPAP or Auto-CPAP device, is intended for use in treating obstructive sleep apnea (OSA) on adult patients (>30 kg). iCodeConnect is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been transmitted from the patient's Luna CPAP or Auto-CPAP therapy device located in the home to the clinician or healthcare professional. iCodeConnect also provides remote settings capabilities.
Device Description	iCodeConnect is a web based patient management system used to store and manage sleep compliance and efficacy data uploaded from a Luna CPAP or Auto-CPAP device. iCodeConnect allows device patient data to be

uploaded using a variety of methods, including manual entry, SD Card, and wireless transmission. Use of wireless transmission (i.e. WiFi) can provide wireless compliance monitoring and remote settings update functions.

For wireless transmission, iCodeConnect consists of the wireless data transmission module Wi-Fi kit and web based iCodeConnect patient management software. TheWi-Fi Kit is intended to be used in conjunction with the Luna CPAP System (E-20C-H-O), Auto-CPAP System (E-20A-H-O / E-20AJ-H-O), which were cleared in K141770.

1) iCodeConnect Software is an analysis and management platform for the patient's therapy data. This platform, adopting the form of a website, not only realizes the uniform management of the patient's data and the information of the provider, the doctor and the patient, but also allows for the Wi-Fi Kit or other wireless communication module to transmit data and remotely updating therapy device settings, which reduces the inconvenience brought by the traditional mailing of SD card and makes data collection more timely.

Wi-Fi Kit is an accessory module that attaches via USB cable to the data output port of a Luna® CPAP or Auto-CPAP devices. The wireless module Wi-Fi Kit uploads the device's therapy data to the iCodeConnect software with the help of off-the-shelf Wi-Fi wireless communication technology. After connecting to the internet, the wireless kit shall automatically collect the user information, statistical information and detailed information in the therapy device for uploading.

Non-Clinical Testing	Non-clinical testing of the iCodeConnect has been

carried out to cover functional verification and device performance. The proposed iCodeConnect has been tested to appropriate standards and other applicable requirements. The device was designed and tested according to:

- IEC 60601-1-2:2014, medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1 Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-1 Medical Electrical Equipment- Part 1-11: General requirements for basic safety and essential performance- Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- ISO14971:2007 Medical devices - Application of risk management to medical devices
- FCC Regulation 47 CFR Part 15 Radio Frequency Devices

Additional design considerations were applied based on published guidance and draft guidance documents from FDA:

1. FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
2. FDA Guidance - Design Considerations for Devices Intended for Home Use (Nov24, 2014)
3. FDA Guidance -Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Oct 2, 2014)

	4. FDA Guidance - Radio Frequency Wireless Technology in Medical Devices (Aug 14, 2013) All tests confirmed that iCodeConnect met the predetermined acceptance criteria and demonstrated substantial equivalence to the predicate device.
Clinical Testing	Clinical testing was not required to demonstrate the safety and effectiveness of the iCodeConnect. The product functionality has been adequately assessed by bench testing as above.

Substantial Equivalence

Features/ Function	Proposed Device	Predicate Device	Comments
	iCodeConnect (510K Number: K160127)	**EasyCare Online** (510K Number: K093684)	
Product Code	BZD	BZD	Same as predicate
Regulation Number	868.5905	868.5905	Same as predicate
Regulation Name	Noncontinuous ventilator (IPPB)	Noncontinuous ventilator (IPPB)	Same as predicate
Intended Use	iCodeConnect, in conjunction with a Luna CPAP or Auto-CPAP device, is intended for use in treating obstructive sleep apnea (OSA) on adult patients (>30 kg). iCodeConnect is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been transmitted from the patient's Luna CPAP or Auto-CPAP therapy device located in the home to the clinician or healthcare professional. iCodeConnect also provides remote settings capabilities.	EasyCare Online is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been transmitted from the patient's flow generator located in the home to the care giver. EasyCare Online also provides remote settings capabilities. It is intended to be used by Clinicians in conjunction with ResMed compatible flow generators.	

Features/ Function	Proposed Device	Predicate Device	Comments
	iCodeConnect (510K Number: K160127)	**EasyCare Online** (510K Number: K093684)	
Device Composition	A web-based software and a wireless module	A web-based software and a wireless module	Same as predicate
Software Function	The iCodeConnect Software is designed to display the data which was uploaded from the CPAP / Auto-CPAP device, store the information in a database and provide a secure interface, allowing the user to query and view patient and treatment information. The iCodeConnect Software supports applying new settings to the CPAP/Auto-CPAP device remotely from the clinician's PC.	The Server System of Easycare Online is designed to display the data which was got from the flow generator, store the information in a database and provide a secure interface, allowing the user to query and view patient and treatment information. The Server System Software supports to apply new settings to the flow generator device remotely from the clinician's PC.	Same as predicate
Remoter Settings Change Function	Flow generator settings can be changed, through wireless module can be made from the clinicians' PC by iCodeConnect Software.	Flow generator settings can be changed, through wireless module can be made from the clinicians' PC by Server System.	Same as predicate
Data Transfer Technology	Wireless	Wireless	Same as predicate
Connectivity	WiFi	GSM	Both the wireless modules are pre-approved.

Features/ Function	Proposed Device	Predicate Device	Comments
	iCodeConnect (510K Number: K160127)	**EasyCare Online** (510K Number: K093684)	
Therapy Setting	Pressure Mode Comfort	Pressure Mode Comfort	Same as predicate
Power Requirements	The wireless module is powered via electrical connection form the flow generator.	The wireless module is powered via electrical connection form the flow generator.	Same as predicate
Environmental Specifications	Operating temperature: 5℃ to 35℃ Operating humidity : 15% ～ 93%, Non-condensing Storage and transport temperature: -25℃ ～ 70℃ Storage and transport humidity: ≤ 93%, Non-condensing	Operating temperature: 5℃ to 35℃ Operating humidity : 10 to 95% non-condensing Storage and transport temperature: -20℃ to 60℃ Storage and transport humidity: 10 to 95% non-condensing	Both the devices meet the requirement.
Degree of Protection Against Electric Shock	Type BF Vertical Applied Part	Type BF Vertical Applied Part	Same as predicate
Degree of Protection Against Ingress of Water	IP22	IP21	Both the devices meet the requirement.
Sterilization/ Reuse	Not provided sterile Reusable with cleaning instructions	Not provided sterile Reusable with cleaning instructions	Same as predicate

Conclusions

Hardware testing carried out for iCodeConnect indicates it meets design and performance functional requirements. Software verification demonstrates that device features and the system configuration functions are substantially equivalent to the predicate device. This information indicates that the iCodeConnect is substantially equivalent to the predicate device.