April 5, 2019

Guangdong Biolight Meditech Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 Cn

Re: K181919
Trade/Device Name: Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: February 19, 2019
Received: February 26, 2019

Dear Diana Hong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K181919

Device Name
Patient Monitor
Model: V9

Indications for Use *(Describe)*
V9 Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO2) and Temperature (Temp).
V9 Patient Monitor is used to monitor vital signals for patients and is intended to be used in controlled, hospital environments. It is applicable for adult, pediatric and neonatal patients. It is not intended for helicopter transport, hospital ambulance or home use.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K181919

1. Date of Preparation: 4/5/2019

2. Sponsor Identification

Guangdong Biolight Meditech Co., Ltd.
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3. Designated Submission Correspondent

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Mr. Chengyu Wang (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Patient Monitor
Model: V9
Classification Name: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)
Classification: II
Product Code: MWI
Regulation Number: 21 CFR 870.2300
Review Panel: Cardiovascular

Indications for Use:
V9 Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO2) and Temperature (Temp).
V9 Patient Monitor is used to monitor vital signals for patients and is intended to be used in controlled, hospital environments. It is applicable for adult, pediatric and neonatal patients. It is not intended for helicopter transport, hospital ambulance or home use.

Device Description
The V9 Patient Monitor can provide the monitoring of physiological parameters such as the Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO2) and Temperature (Temp). The V9 Patient Monitor is a portable device, consists of main unit and accessories, including NIBP cuff, Temperature sensor, CO2 sensor and SpO2 sensor.

It consists of main unit and accessories, including NIBP cuff, Temperature sensor, CO2 sensor and SpO2 sensor.

All modules, boards and accessories used in V9 Patient Monitor has already been cleared by FDA, referring to Table 1. In which, two NIBP and three SpO2 modules are optional for proposed device.

Table 1. List of 510(k) of Modules

Module		510(k) Number
NIBP	BLT NIBP Module	K153135
	Suntech NIBP Module	K152552
SpO2	Nellcor SpO2 Module	K052186
	MASIMO SpO2 Module	K101896
	BLT SpO2 Module	K153135
Temperature	Temperature Module	K153135
CO2	CO2 Module	K153135

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
- 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 60601-1-8: 2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 80601-2-30:2013 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 80601-2-61:2011 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 80601-2-55:2011 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56: 2009 Medical electrical equipment – Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.
- ANSI C63.27-2017 American National Standard For Evaluation Of Wireless Coexistence

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device predicate.

6. Clinical Test Conclusion

No clinical study is included in this submission, because all modules have been previously cleared by FDA. The K Number of each module is listed in Table 1 of this document.

7. Identification of Predicate Device

Predicate Device
510(k) Number: K153135
Product Name: V6 Vital Signs Monitor

8. Substantially Equivalent (SE) Comparison

Table 2 Substantially Equivalent Comparison

ITEM	**Proposed Device**	**Predicate Device** Vital Signs Monitor V6, K153135
Product Code	MWI	MWI
Regulation Number	21 CFR 870.2300	21 CFR 870.2300
Class	II	II
Indications for Use	V9 Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO2) and Temperature (Temp). V9 Patient Monitor is used to monitor vital signals for patients and is intended to be used in controlled, hospital environments. It is applicable for adult, pediatric and neonatal patients. It is not intended for helicopter transport, hospital ambulance or home use.	The vital signs monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO2) and Temperature (Temp). This vital signs monitor is used to monitor vital signals for patients and is suitable for use in hospital environments including out-patient department, wards and NICU. It is not intended for helicopter transport, hospital ambulance or home use. And it is applicable for adult, pediatric and neonatal patients.
Intended Population	The monitors are intended for adult, pediatric and neonatal.	The monitors are intended for adult, pediatric and neonatal.
Intended Environment	The V9 Patient Monitor is used to be used in hospital environments including out-patient outpatient departments, wards and NICU. It is not intended for helicopter transport, hospital ambulance or home use.	The vital signs monitor is used to be used in hospital environments including out-patient outpatient departments, wards and NICU. It is not intended for helicopter transport, hospital ambulance or home use.
Power Supply	The monitors can be supplied by AC power.	The monitors can be supplied by AC power.
Number of Patient be monitored each time	Single patient each time	Single patient each time
Sterile	No	No
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2

Alarm Function	Comply with IEC60601-1-8	Comply with IEC60601-1-8
SpO2 Module	BLT, Nellcor and Masimo Comply with IEC 80601-2-61	BLT and Nellcor Comply with IEC 80601-2-61
NIBP Module	BLT and Suntech Comply with IEC 80601-2-30	BLT Comply with IEC 80601-2-30
CO2 Module	Comply with ISO 80601-2-55	Comply with ISO 80601-2-55
Temp Module	Comply with ISO 80601-2-56	Comply with ISO 80601-2-56
Patient Contact Accessories	SpO2 Sensor, NIBP cuff, CO2 Sensor and Temp Sensor	SpO2 Sensor, NIBP cuff, CO2 Sensor and Temp Sensor
Biocompatibility	All the patient contact accessories were previously cleared by FDA	All the patient contact accessories were previously cleared by FDA

The SpO2 and NIBP module of proposed device and predicate device is different. Masimo SpO2 and Suntech NIBP are not included in predicate device, however, the Masimo SpO2 and Suntech NIBP have been cleared by FDA under K131898 and K152552. Therefore, this difference is considered not to affect the substantially equivalency (SE) between the proposed and predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.