



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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Silver Spring, MD 20993-0002

February 25, 2016

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

Re: K153135

Trade/Device Name: V6 Vital Signs Monitor  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)  
Regulatory Class: Class II  
Product Code: MWI  
Dated: January 21, 2016  
Received: January 27, 2016

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. 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153135

Device Name

Vital Signs Monitor V6

Indications for Use (Describe)

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 (SpO<sub>2</sub>), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO<sub>2</sub>) 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.

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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*"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."*

## **Exhibit#1 510(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: \_\_\_\_\_

1. Date of Preparation: 01/21/2016

2. Sponsor Identification

Establishment Registration Number: 3007305624

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)

Lee Fu (Alternative Contact Person)

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#### 4. Identification of Proposed Device

Trade Name: Vital Signs Monitor

Common Name: Vital Signs Monitor

Model(s): V6

##### Regulatory Information

Classification Name: Patient Monitor

Classification: II

Product Code:MWI

Regulation Number: 21 CFR 870.2300

Review Panel:Cardiovascular

Indication for 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 (SpO<sub>2</sub>), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO<sub>2</sub>) 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.

##### Device Description

The Vital Signs Monitor is a portable device intended for use by health care professionals. The monitor could provide the monitoring of physiological parameters such as the Oxygen Saturation (SpO<sub>2</sub>), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO<sub>2</sub>) and Temperature (Temp).

The following lists the detailed features of the subject device.

- LCD/LED display
- SpO<sub>2</sub>, Pulse Rate NIBPCO<sub>2</sub> and TEMP measurement
- Infrared ear temp or fast temp module for Temp measurement
- Nellcor or Masimo or BLT SpO<sub>2</sub> module
- Display numeric and waveform information simultaneously
- Nurse call feature
- Built-in Lithium-ion Battery
- Suitable for adult, pediatric and neonate patients
- Visual and audible alarm

#### 5. Identification of Predicate Device(s)

Predicate Device 1

510(k) Number: K113833

Product Name: Vital signs monitor

Model Name: V6

Predicate Device 2

510(k) Number: K003313

Product Name: Filac Fast Temp

Model Name: F3000

6. 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 Electrical Safety
- IEC 60601-1-2 Electromagnetic Compatibility
- IEC60601-1-8 Requirements of alarm function
- IEC80601-2-30 Requirements for basic safety and essential performance of NIBP
- IEC80601-2-61 Requirements for basic safety and essential performance of pulse oximeter equipment
- Clinical Electronic Thermometers testing for the newly added F3000 Temperature Module pursuant to the guidance “Guidance on the Content of Premarket Notification [510(K)] Submission for Clinical Electronic Thermometers” dated Mar. 1993.

7. Clinical Test Conclusion

No clinical study is included in this submission.

## 8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics(V6)

Item	Proposed Device(s)	Predicate Device(s) Vital Signs Monitor V6 K113833
Product Code	MWI	MWI
Regulation Number	870.2300	870.2300
Intended Use	The Vital Signs Monitor V6 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). The Vital Signs Monitor V6 is intended to be use in outpatient departments and emergency treatment rooms of hospitals, community clinics, private clinics and other medical institutions. It is not intended for helicopter transport, hospital ambulance or home use.	The Vital Signs Monitor V6 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). The Vital Signs Monitor V6 is intended to be use in outpatient departments and emergency treatment rooms of hospitals, community clinics, private clinics and other medical institutions. It is not intended for helicopter transport, hospital ambulance or home use.
Configuration	NIBP	NIBP
	SpO2	SpO2
	CO2	CO2
	Quick Temp	Infrared temp
Sterile	N/A	N/A
Single Use	N/A	N/A
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10
Electrical Safety	IEC 60601-1	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2

Table 2 General Comparison to Filac Fast Temp

ITEM	Proposed Device	Predicate Device
Measurement range	30 to 42 °C	30 to 42 °C
Resolution	0.1 °C	0.1 °C
Unit	°C	°C, °F
Update time	Every 1s	Every 1s
Self-checking	Every 3s	Every 3s
Accuracy	Monitor mode, Predictive mode: $\leq \pm 0.1$ °C Quick mode: $\pm 0.2$ °C	Monitoring Mode and Predictive mode: $\pm 0.1$ °C Quick Predictive Mode: $\pm 0.3$ °C
Response time	Predictive Mode: $\leq 10$ seconds Monitoring Mode(all sites): 120 ~180 seconds	Oral(Quick Predictive Mode):3~5 seconds(non-fever temps); 8~10 seconds (fever temps) Oral(Predictive Mode):6~10 seconds Axillary:8~12 seconds Rectal:10~14 seconds Monitoring Mode(all sites):60~120 seconds

9. Substantially Equivalent (SE) Conclusion

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