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

May 24, 2017

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

Re: K170514
Trade/Device Name: M6000C Central Monitoring System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: February 14, 2017
Received: February 21, 2017

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,

for 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)*
K170514

Device Name
M6000C Central Monitoring System

Indications for Use *(Describe)*
Central Monitoring System Software is intended to conduct centralized monitoring of adult, pediatrics and neonatal patient's vital sign information from compatible bedside monitors. The software collects, stores, displays and alarms the information provided on the bedside monitor. The monitoring parameters include Electrocardiogram(ECG), Heart Rate(HR), Respiration(RESP), Pulse Oxygen Saturation(SpO2), Pulse Rate(PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure(IBP), Impedance Cardiograph(ICG), TEMP(Temperature), Carbon dioxide (CO2), Anesthetic Gas (AG), Fetal Heart Rate (FHR), Uterine contraction (TOCO) and Fetal Movement (FM) etc. It is intended to be used in the hospital or medical institutions, and it is not intended for 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Tab #6 510(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: K170514

1. Date of Preparation: 05/04/2017

2. Sponsor Identification

Guangdong Biolight Meditech Co., Ltd.
No.2 Innovation First Road, Technology Innovation Coast,
Hi-Tech Zone, Zhuhai, Guangdong, 519085, P.R. China

Establishment Registration Number: 3007305624
Contact Person: Jin Liang
Position: R&D Director
Tel: +86-756-3399967
Fax: +86-756-3399989
Email: liang_j@blt.com.cn

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Cindy Wang (Alternative Contact Person)
Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Central Monitoring System
Common Name: Central Monitoring System
Model(s): M6000C
Regulatory Information
Classification Name: Perinatal monitoring system and accessories
Classification: II;
Product Code: MHX;
Regulation Number: 21 CFR 870.1025;
Review Panel: Cardiovascular;

Intended Use Statement:

Central Monitoring System Software is intended to conduct centralized monitoring of adult, pediatrics and neonatal patient's vital sign information from compatible bedside monitors. The software collects, stores, displays and alarms the information provided on the bedside monitor. The monitoring parameters include Electrocardiogram(ECG), Heart Rate(HR), Respiration(RESP), Pulse Oxygen Saturation(SpO2), Pulse Rate(PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure(IBP), Impedance Cardiograph(ICG), TEMP(Temperature), Carbon dioxide (CO2), Anesthetic Gas (AG), Fetal Heart Rate (FHR), Uterine contraction (TOCO) and Fetal Movement (FM) etc. It is intended to be used in the hospital or medical institutions, and it is not intended for home use.

Device Description:

M6000C central monitoring system software, the risk management object, can central monitor significant vital sign parameters of multi-patients, including ECG/HR, RESP, SpO2, PULSE, NIBP, IBP, ICG, TEMP, CO2, AG, FHR, TOCO and FM. It is connected by network with bedside units and receives data from bedside units. Then, the data are displayed on the screen or recorded or printed as per needs. When the monitored data exceed a set value, the central monitoring system software will start alarm system and gives out alarm to remind doctors and nurses for attention.

5. Identification of Predicate Device and Reference Device

Predicate Device
510(k) Number: K120727
Product Name: Central monitoring system
Model Name: MFM-CMS

Reference Device
510(k) Number: K153580
Product Name: Central monitoring system
Model Name: M6000C

6. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The Central Monitoring System also complies with voluntary standards for medical devices.

The test results demonstrated that the proposed device complies with the following standards:

- EN ISO 14971: 2012 Medical Device Risk Management
- IEC 62366: 2007 Medical Devices - Application of Usability Engineering to Medical Devices

The following data were provided to support the substantial equivalence determination:

- Performance testing was conducted to verify that the Central Monitoring System Software is compatible with various bedside monitors.
- Performance testing was conducted to verify that the data latency rates were acceptable for the clinical environment.
- Software verification and validation testing as recommended in FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005)

Please note that the subject is a software only product, EMC and Electrical Safety Evaluation are not required.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device Central Monitoring System Truscope CNS	Predicate Device
Product Code	MHX	MHX
Regulation No.	870.1025	870.1025
Class	II	II
Intended Use	Central Monitoring System Software is intended to conduct centralized monitoring of adult, pediatrics and neonatal patient's vital sign information from compatible bedside monitors. The software collects, stores, displays and alarms the information provided on the bedside monitor. The monitoring parameters include Electrocardiogram(ECG), Heart Rate(HR), Respiration(RESP),	MFM-CMS provided centralized monitoring and critical care management for patients monitored by EDAN bedside monitors, From MFM-CMS, clinicians can gain access to patient information from patients on the Network. MFM-CMS display waveforms , parameters and alarm status of EDAN bedside monitors for up to 32 patients on a single screen or up to 64 patients

	Pulse Oxygen Saturation(SpO2), Pulse Rate(PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure(IBP), Impedance Cardiograph(ICG), TEMP(Temperature), Carbon dioxide (CO2), Anesthetic Gas (AG), Fetal Heart Rate (FHR), Uterine contraction (TOCO) and Fetal Movement (FM) etc. It is intended to be used in the hospital or medical institutions, and it is not intended for home use.	using two screens
Network	Wired and Wireless	Wired and wireless
Display	Patient demography data, and notes. Providing the means to display multiple beds simultaneously.	Waveforms and notes Providing the means to display multiple beds simultaneously
Print	Print Patient's monitoring records	Print Patient's monitoring records
Archive	Providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk). Providing automatic archiving of the data.	Providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk). Providing automatic archiving of the data.
Alarm	Visual alerts of out-of-limit data	Visual alerts of out-of-limit data
Electronic patient record	Easy interfacing with any IT patient record system for data acquisition, viewing and storage of electronic patient record.	Easy interfacing with any IT patient record system for data acquisition, viewing and storage of electronic patient record.
Notes	Providing the user the ability to enter comments and specific data.	Providing the user the ability to enter comments and specific data.
Complied Standard	IEC 62304	IEC 62304

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.