DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 7, 2016

Guangdong Biolight Meditech Co., Ltd.
% Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai 200237
CHINA

Re: K153580
Trade/Device Name: Central Monitoring System Software
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal Monitoring System and Accessories
Regulatory Class: Class II
Product Code: HGM
Dated: August 5, 2016
Received: August 8, 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,

For Division

Douglas Silverstein -S
2016.09.07 15:26:22 -04'00'

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K153580

Device Name
Central Monitoring System Software

Indications for Use *(Describe)*
Central Monitoring System Software is intended to conduct centralized antepartum and intrapartum monitoring of pregnant women'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). 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.

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510(k) Summary

K153580

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

1. Date of Preparation: 09/06/2016

2. Sponsor Identification

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

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4. Identification of Proposed Device
Trade Name: Central Monitoring System Software
Common Name: Central Monitoring System Software
Model(s): Truscope CNS/ M6000C

Regulatory Information

Classification Name: Perinatal monitoring system and accessories
Classification: Class II
Product Code: HGM, system, monitoring, perinatal
Regulation Number: 21 CFR 884.2740
Review Panel: Obstetrics/Gynecology

5. Identification of Predicate Device(s)

510(k) Number: K103172
Product Name: Obstetrical Data Management and Monitoring Software Application
Model Name: CIV-OB (PLUS)

6. Device Description

The Central Monitoring System Software is a software-only device that is intended to conduct centralized antepartum and intrapartum monitoring of pregnant women's vital sign information from compatible bedside monitors connected by a wired or wireless network. The Central Monitoring System consists of

two models: M6000C and Truscope CNS. Both models provide functions including collecting, storing, displaying, and alarming (e.g. when the monitored data exceeds a set value, the device will alarm to alert medical personnel) the information which is received from the bedside monitor(s). Multiple patients can be monitored simultaneously. Parameters monitored include ECG/HR, RESP, SpO2, PULSE, NIBP, IBP, ICG, TEMP, CO2, AG, FHR, TOCO and FM.

7. Indications for Use

Central Monitoring System Software is intended to conduct centralized antepartum and intrapartum monitoring of pregnant women'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). It is intended to be used in the hospital or medical institutions, and it is not intended for home use.

8. Predicate Comparison

Item	Proposed Device(s)	Predicate Device(s)
Product Code	HGM	HGM
Regulation Number	21 CFR 884.2740	21 CFR 884.2740
Intended Use	Central Monitoring System Software is intended to conduct centralized antepartum and intrapartum monitoring of pregnant women'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). It is intended to be used in the hospital or medical institutions, and it is not intended for home use.	The CIVNET CIV-obTM (plus) is a clinical data managing software application and is indicated for antepartumn and intrapartumn monitoring of pregnant women in a healthcare setting. The CIVNET CIV-obT* (plus) is indented to manage perinatal monitoring data acquired from bedside monitors or manual inputs for viewing at the central nursing station. The system also produces an electronic medical record. The CIYNET CIV-ob1~" (plus) has display fields for the following obstetric data: • Monitoring site details • Patient demographics, • Provider notes, • fetal heart rate (FHR), • uterine activity(via tocodynamometry or IUP) • Head Decent • Cervix Dilation
Sterile	Not applicable	Not applicable

Single Use	Not applicable	Not applicable
Biocompatibility	Not applicable	Not applicable
Network connecting to bedside monitor	Wired and Wireless	Wired
Display	Fetal heart rate, TOCO, maternal vital signs, patient demographic data, and notes. Providing the means to display multiple beds simultaneously.	Fetal heart rate, TOCO, maternal vital signs, patient demographic data, and notes. Providing the means to display multiple beds simultaneously.
Print	Print (locally or remotely) CTG, patient record	Print (locally or remotely) CTG, patient records s, and CIV-ob TM (plus) data base definition (e.g. item names).
Archive	CTG and maternal vital signs. Providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk). Providing automatic archiving of the data.	CTG and maternal vital signs. Providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk). Saving data automatically.
Alarm	Visual alerts of fetal/maternal monitor such as out-of-limit heart rate or poor signal quality.	Visual alerts of fetal/maternal monitor such as out-of-limit heart rate or poor signal quality.
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.
Remote Access	Review fetal/maternal monitor data	Review fetal/maternal monitor data

Central Monitoring System Software and the predicate device do not have identical indication for use statements; however, they have the same intended use (centralized antepartum and intrapartum monitoring of pregnant women's vital sign information).

In addition, there are differences in the device technological characteristics. The predicate device uses a wired network to connect to the bedside units, while the subject device gives the option of a wired or wireless network. Wireless networks are widely used for various applications. There are also differences in the parameters that the subject device and predicate collect, store, display and alarm. These differences do not raise different questions of safety as compared to the predicate device.

9. Non-Clinical Testing

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:

- IEC 62366: 2007 Medical Devices - Application of Usability Engineering to Medical Devices
- IEC 62304: 2006 Medical Device Software - Software Life Cycle Process

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)

10. Substantially Equivalent (SE) Conclusion

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