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

January 6, 2016

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

Re: K151287
Trade/Device Name: Fingertip Pulse Oximeters M70, M70A, M70B, M70C, M70D
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 2, 2015
Received: December 7, 2015

Dear Ms. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
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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)*
K151287

Device Name
Fingertip Pulse Oximeters M70, M70A, M70B, M70C, M70D

Indications for Use *(Describe)*
The Fingertip Pulse Oximeter is intended to measure functional arterial oxygen saturation (SpO2) and pulse rate of adult, child and adolescent patients in hospital, hospital type facilities, as well as in the home care environment.
The oximeter is not suitable to monitor patient continuously for long term.

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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Tab #7 510(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: K151287

1. Date of Preparation: 01/06/2016

2. Sponsor Identification

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

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Fingertip Pulse Oximeters
Common Name: Pulse Oximeter
Models: M70, M70A, M70B, M70C, M70D

Regulatory Information

Classification Name: Oximeter
Classification: 2
Product Code: DQA
Regulation Number: 21 CFR 870.2700
Review Panel: Anesthesiology

Intended Use Statement:
The Fingertip Pulse Oximeter is intended to measure functional arterial oxygen saturation (SpO_2) and pulse rate of adult, child and adolescent patients in hospital, hospital type facilities, as well as in the home care environment.
The oximeter is not suitable to monitor patient continuously for long term.

Device Description

The proposed devices, Fingertip Pulse Oximeters M70, M70A, M70B, M70C and M70D are fingertip devices, which can display %SpO_2, pulse rate value, waveform pulse amplitude bar indication.

The five models share the same configuration, function, intended use, safety and performance, the only difference is extrinsic feature.

The proposed devices, Fingertip Pulse Oximeters M70, M70A, M70B, M70C and M70D are modified versions of the predicate device, M70, cleared under K081712. The oximetry technology including the sensor was unchanged.

Because the predicate device cleared under K081712 is only indicated for adult use and the subject device models are indicated for both adult and pediatric use, an additional predicate device was cited (cleared under K141128). Please refer to the substantial equivalence table below for a comparison between the technological characteristics of the subject device models and the device cleared under K141128.

5. Identification of Predicate Devices

Predicate Device 1

510(k) Number: K081712
Product Name: Fingertip Pulse Oximeter
Model Name: M70

Predicate Device 2

510(k) Number: K141128
Product Name: Fingertip Pulse Oximeter
Mode Name: MD300CL37

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: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: 2007, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
- ISO 80601-2-6: 2011, Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment.

7. Clinical Test Conclusion

Because the differences between the subject device models and predicate device cleared under K081712, no additional clinical performance testing was needed.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Devices	Predicate Device 1 (K081712)	Predicate Device 2 (K141128)
Product Code	DQA	DQA	DQA
Regulation Number	21 CFR 870.2700	21 CFR 870.2700	21 CFR 870.2700
Class	Class II	Class II	Class II
Intended Use	The Fingertip Pulse Oximeter is intended to measure functional arterial oxygen saturation (SpO_2) and pulse rate of adult, child and adolescent patients in hospital, hospital type facilities, as well as in the home care environment. The oximeter is not suitable to monitor patient continuously for long term.	The M70 fingertip pulse oximeter is intended to measure functional arterial oxygen saturation (SpO_2) and pulse rate of adult patients in hospital, hospital type facilities, as well as in the home care environment. The oximeter is not suitable to monitor patient continuously for long term.	The Fingertip Pulse Oximeter MD300CL37 is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, adolescent, child and infant patients in hospital, hospital type facilities, and home environment.
Configuration	Detector and emitter LED, OLED display module, CPU and power supply module.	Detector and emitter LED, OLED display module, CPU and power supply module.	Detector and emitter LED, OLED display module, CPU and power supply module.
Working Mode	Spot Checking	Spot Checking	Spot Checking
Theory of Operation	Fingertip	Fingertip	Fingertip
Wavelengths	RED: 660 nm Infrared: 905 nm	RED: 660 nm Infrared: 905 nm	RED: 660 nm Infrared: 940 nm
SpO_2 Measuring Range	0%-100%	0%-100%	0～99%
SpO_2 Accuracy	70~100%, ±2%	70~100%, ±2%	70%～99%: ±3%;
PR Measuring Range	25~250 bpm	25~250 bpm	30~235 bpm
PR Accuracy	±1% or ± 1 bpm, whichever is greater	±1% or ± 1 bpm, whichever is greater	30～99bpm, ±2bpm; 100～235bpm, ±2%
Single Use/Reuse	Reuse	Reuse	Reuse
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Complied with IEC 60601-1
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2
Performance	Complied with ISO80601-2-61	Complied with ISO80601-2-61	Complied with ISO80601-2-61
Patient Contact	Silica Gel Patch: Medical	Silica Gel Patch: Medical	Silica Gel Patch: Medical

Material	Silicon	Silicon	Silicon

9. Substantially Equivalent (SE) Conclusion

As per the technological characteristics of the subject device models are the same or similar to those of the predicate device cleared under K141128. Of note is that the pulse rate and SpO_2 specifications are more accurate for the subject device models than those for the device cleared under K141128.

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