SEP 1 2 2008

K081712

Chapter III 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is: _____

1. Sponsor

Guangdong Biolight Meditech Co., Ltd
Innovation First Road, Technology Innovation Coast
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Contact Person: Mr. Tianbao Li, Chief Engineer
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E-mail: li_tb@blt.com.cn

2. Submission Correspondent

Ms. Diana Hong
Mr. Lee Fu
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Shanghai, China 20020
Phone: +86-21-64264467
Fax: 760-466-5084
Email: Diana.hong@mid-link.net

3. Subject Device Information

a. M70 Fingertip Pulse Oximeter

(1) Classification Name: Oximeter
(2) Regulation Number:870.2700
(3) Product Code:DQA
(4) Class: II
(5) Review Panel: Anesthesiology

b. M700 Handheld Pulse Oximeter

(1) Classification Name: Oximeter

(2)Regulation Number:870.2700
(3)Product Code: DQA
(4)Class: II
(5)Review Panel: Anesthesiology

4. Predicate Device

a. Fingertip Oximeter MD300C
K-number: K070371
Product Code: DQA
Intended Use:
Fingertip Pulse Oximeter MD300C is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care and etc). Not for continuously monitoring.
Manufactured by:
Beijing Choice Electronic Technology Co., Ltd.
Room 1127-1128 Building B, Bailangyuan
Fuxing Road , No. A36
Beijing, CHINA 100039

b. PM-60 Pulse Oximeter
K-number: K072581
Product Code: DQA
Intended Use:
The PM-60 handheld Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult, pediatric and neonatal patients in hospitals, out-of-hospital transport and home care.
Manufactured by:
Shenzhen Mindray Bio-medical Electronics Co., LTD.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park
Nanshan, Shenzhen, 518057, P.R.China

5. M70 Fingertip Pulse Oximeter

5.1 Device Description

The subject device of M70 Fingertip Pulse Oximeter is a fingertip device, which can display %SpO2, pulse rate value, waveform pulse amplitude bar indication.

The subject device consists of detector and emitter LED, OLED display module, CPU, driving circuit, power supply circuit and battery.

The operational principle of subject device uses the method as mensurated optical density by spectrophotometer. It is base on the double wavelength Lambert Beer's Law and uses the specific absorbance of oxygenation hemoglobin and deoxyhemoglobin to calculate.

The subject device is not for life-supporting or life-sustaining, not for implant. The device is not sterile and does not need sterilization or re-sterilization. The device is for prescription. The device does contain drug or biological product.

5.2 Statement of Intended Use:

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.

5.3 Testing

Laboratory testing was conducted to validate and verify that M70 Fingertip Pulse Oximeter met all design specifications, including electrical safety, EMC, biocompatibility, specification. Results of these tests demonstrate compliance to the requirements of all consensus standards

5.4 Substantially Equivalence Determination

Comparison Analysis

The subject device has same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device. The only difference is Measurement Wavelengths, Working time, Operating temperature, PR Measuring range, Atmosphere pressure.

Conclusion:
The subject device is Substantially Equivalent (SE) to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.

6. M700 Handheld Pulse Oximeter

6.1 Device Description

The subject device of M700 Handheld Pulse Oximeter is a handheld device, whose mainly function are display %SpO_2, pulse rate value, pulse amplitude bar indication.

The operational principle of subject device uses the method as mensurated optical density by spectrophotometer. It is base on the double wavelength Lambert Beer's law and uses the specific absorbance of oxygenation hemoglobin and deoxyhemoglobin to calculate.

The subject device consists of detachable SpO_2 sensor, Main Frame and Battery. The Main Frame consist two parts, which is Control Module and SpO2 Module.

The subject device has 6 model sensors as the accessory, they are listed below:

A0212-SA103PV (for Adult)
A0212-SP103PV (for Pediatric)
A0212-SW103PU (for Neonate)
RSJ091DA (for Adult)
RSJ091DI (for Pediatric)
RSY091DN (for Neonate)

6.2 Statement of Intended Use

The M700 handheld pulse oximeter is indicated for spot checking of functional arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric and neonatal patients in hospital, hospital type facilities as well as in the home care environment.

6.3 Testing

Laboratory and Clinical testing was conducted to validate and verify that M700 Handheld Pulse Oximeter met all design specifications, including electrical safety, EMC, biocompatibility, specification. Results of these tests demonstrate compliance to the requirements of all consensus standards

6.4 Substantially Equivalence Determination

Comparison Analysis

The subject device has same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device. The only difference is Measurement Wavelengths, Display Unit, Power, Working time, Operating temperature, PR Measuring range, Relative humidity, Atmosphere pressure.

Conclusion:

The subject device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2008

Guangdong Biolight Meditech Company, Limited
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General Manager
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No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030
CHINA

Re: K081712
Trade/Device Name: M700 Handheld Pulse Oximeter
M70 Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 13, 2008
Received: June 17, 2008

Dear Ms. Hong:

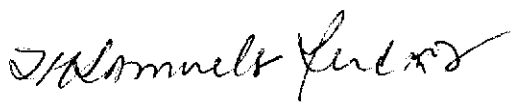
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indication for Use

510(k) Number (if known): _____

Device Name: M70 Fingertip Pulse Oximeter

Indications for Use:

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.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081712

Indication For Use

510(k) Number (if known): _____

Device Name: M700 Handheld Pulse Oximeter

Indications for Use:

The M700 handheld pulse oximeter is indicated for spot checking of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric and neonatal patients in hospital, hospital type facilities as well as in the home care environment.

Prescription Use ___√___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081712