K101694

Exhibit #3 510(k) Summary

SEP 0 8 2010

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: K101694

Date of Preparation	11 JUN 2010
Sponsor	**Guangdong Biolight Meditech Co., Ltd [Reg #:3007305624]** Innovation First Road, Technology Innovation Coast Zhuhai, Guangdong, 519085, China Contact Person: Mr. Tianbao Li, Chief Engineer Tel: +86-756-3399963 | Fax: +86-756-3399989 | E-mail: li_tb@blt.com.cn
Submission Correspondent	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Suite 5D, No.19, Lane 999, Zhongshan Road (S-2), Shanghai, 200030, China T: +86-21-64264467 | F: 240-238-7587 | E: info@mid-link.net
Proposed Device	**M800 Handheld Pulse Oximeter** Modification to: M700 Handheld Pulse Oximeter (K081712) as predicate device 21 CFR 870.2700 | DQA | Class II
Intended Use	M800 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.
Device Description	The proposed device is a handheld device, which can display %SpO2, waveform, pulse rate value, pulse amplitude bar indication. It consists of detector and emitter LED, OLED display module, CPU, driving circuit, power supply circuit and battery. In addition, it has alarming function including physical parameter alarming and technical alarming. The physical alarming limit can be set by user. The modifications to M700 Handheld Pulse Oximeter are presented in Table 3-1 Modifications List on the next page.
Test Summary	Per the risk management during the design change control, the verification tests performed demonstrated that risks of each hazard are reduced to acceptable region.
Conclusion	The information in this 510(k) Summary demonstrate that the proposed device, M800 Handheld Pulse Oximeter, is Substantially Equiavlent (SE) to the predicate device, M700 Handheld Pulse Oximeter (K081712), with respect of effectiveness and safety.

Table 3-1 Modifications List

ITEM	M700 Handheld Pulse Oximeter (Predicate / Existed)	M800 Handheld Pulse Oximeter (Proposed / Modified)
Display	LED Display, which can display the following information: Pulse Rate SpO_2 Pulse Strength System Information Status Information.	OLED Display, which can display the following information: Pulse Rate SpO_2 Pulse Strength System Information Status Information. In addition, it can display: SpO_2 waveform, Alarming Limit and Alarming Information.
Audio	Beeper, which can audio indicate the followings: Sensor Detachment Indicating; Pulse Indicating; Key Pressing Indicating; Low Voltage Indicating;	Speaker, which can audio indicate the followings: Sensor Detachment Indicating; Pulse Indicating; Key Pressing Indicating; Low Voltage Indicating; In addition, it can indicate: Starting and Alarming.
Alarming	Without Alarming Function	With Alarming Function

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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Shanghai China 200030

SEP 0 8 2010

Re: K101694
Trade/Device Name: M800 Handheld Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 11, 2010
Received: August 11, 2010

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.

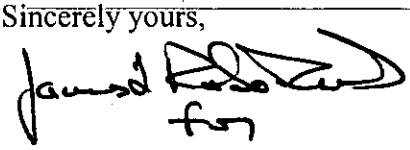
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section III Indication for Use Form

SEP 0 8 2010

510(k) NUMBER (if known):

DEVICE NAME: M800 Handheld Pulse Oximeter

INDICATION FOR USE:

M800 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 ___X___ (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: K101694