Section 3 510 (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: K082789

JAN – 7 2009

1. Subject Device Information:

Device Trade Name: G1B Pulse Oximeter

Device Common Name: Oximeter

Device Classification Name: Oximeter

Product Code: QA

Regulation Number: 21 CFR 870.2700

Panel: Anesthesiology

Indication for Use:
G1B Pulse Oximeter 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.

Sponsor Name and Address:

GENERAL MEDITECH, INC.
South Office 4/F, Kezhi Rd. No.1st. West, Science Park,
Nanshan, Shenzhen, Guangdong, P.R.China
Mr. Carter Wu
Quality Director
Tel: +86 755 2654 6289
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Correspondent Name and Address:

Ms. Diana Hong
Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd

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Zhongshan No.2 Road(S), Shanghai, 200030, China
Tel: +86-21-64264467
Fax: (760)466-5084
Email: Diana.hong@mid-link.net

2. Predicate Device Information

K Number: K072825

Device Name: Fingertip Pulse Oximeter MD300I

Manufacturer: Beijing Choice Electronic Technology Co., LTD

Indication for 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 continuous monitoring.

3. Device Description

The G1B is a flexible, portable, battery powered Pulse Oximeter. The G1B Pulse Oximeter acquires the physiological signals - oxygen saturation (SpO2) and pulse rate (PR). The signals are converted into digital data and processed, and the SpO2 and pulse rate values are calculated and displayed on LED screen.

G1B uses a two-wavelength pulsatile system - red and infrared light - to obtain SpO2 based on the different light absorption of oxygenated and reduced hemoglobin. The light source in the finger sensor emits red and infrared light, which are partially absorbed and modulated by the arterial blood pulsation at the sensor site. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The electronic signals are sent to the oximeter and processed by the oximeter's circuitry. Thereafter, the SpO2 and pulse rate are obtained and indicated on the LED screen.

4 .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

5. SE Determination

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

JAN - 7 2009

General Meditech, Incorporated
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, No.19 Lane 999
Zhongshan No. 2 Road(S)
Shanghai
CHINA 200030

Re: K082789
Trade/Device Name: G1B Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 23, 2008
Received: December 23, 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.

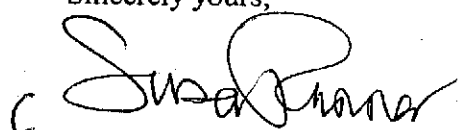
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



for Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number: K082789

Device Name: G1B Pulse Oximeter

Indications for Use:

G1B Pulse Oximeter is a portable non-invasive, spot-checking, 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 continuous monitoring.

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: K082789