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Section III 510(k) Summary

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

The assigned 510(k) Number: K112804

1. Date of Submission: September 26, 2011

2. Sponsor

   Guangdong Biolight Meditech Co., Ltd
   Innovation First Road, Technology Innovation Coast,
   Zhuhai, Guangdong, 519085, China

   Establishment Registration Number: 3007305624

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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
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   Fax: 240-238-7587
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4. Proposed Device Identification

   Proposed Device Name: Fingertip Pulse Oximeter
   Proposed Device Model: M70A, M70B, M70C, M70D

   Classification: Class II

Product Code: DQA
Regulation Number: 21 CFR 870.2700
Review Panel: Anesthesiology

Intended Use Statement:
The Fingertip Pulse Oximeters M70A, M70B, M70C and M70D, are 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 oximeters are not suitable to monitor patient continuously for long term.

5. Predicate Device Identification

510(k) Number: K081712
Product Name: M70 Fingertip Pulse Oximeter
Manufacturer: Guangdong Biolight Meditech Co., Ltd

6. Device Description

The proposed devices of Fingertip Pulse Oximeters M70A, M70B, M70C and M70D are fingertip devices, which can display %SpO2, pulse rate value, waveform pulse amplitude bar indication.

The four models share the same configuration, function, intended use, safety and performance, the only difference is external appearance.

7. Substantially Equivalent Conclusion

The proposed devices, Fingertip Pulse Oximeters M70A, M70B, M70C and M70D, are determined to be Substantially Equivalent (SE) to the predicate device, M70 Fingertip Pulse Oximeter (K081712), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Guangdong Biolight Meditech Company Limited
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
P.O. Box 237-023
Shanghai
China 200237

JAN 27 2012

Re: K112804
Trade/Device Name: Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DOA
Dated: December 28, 2011
Received: December 29, 2011

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,

for Anthony D. Watson

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 II Indications for Use

510(k) Number:
Device Name: Fingertip Pulse Oximeter

Indications for Use:
The Fingertip Pulse Oximeters M70A, M70B, M70C and M70D, are 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 oximeters are not suitable to monitor patient continuously for long term.

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

510(k) Number: K112804

☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D)

☐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)