510(K) SUMMARY

Date Summary Prepared: July 30. 2014

JUL 3 0 2014

Sponsor Information:

Company Name:	BIO Medical Technologies Co., Ltd.(BMT)
Address:	Megu Bldg #431-17 Shindang-dong, Jung-gu Seoul, Republic of Korea 100-452
Contact:	Bruce Lee
Telephone:	+(82) 222340782
FAX:	+(82_ 222340748

Correspondent Contact Information:

Company Name:	Paladin Medical, Inc.
Address:	P.O. Box 560 Stillwater, MN 55082
Contact:	Elaine Duncan, M.S.M.E., RAC
Title:	President
Telephone:	+(82) 222340782
FAX:	+(82_ 222340748

DEVICE INFORMATION:

- Proprietary Name: OxiprobE
- Common Name: Oximetry Sensor
- Classification Name: Oximeter
- Regulation Number: 870.2700
- Classification Product Code: DQA
- Classification/Review Advisory Committee: Anesthesiology

DESCRIPTION of the DEVICE:

The OxiprobE Pulse Oximetry Sensors are used for non-invasive measurement of blood oxygen saturation and pulse rate measurement. The disposable sensors are designed to enable the sensor's light source and photo detector to be securely and properly positioned on the patient. The adhesive stabilizes these important optical components and provides a comfortable fit. The adhesive sensors are patient-dedicated and can travel with the patients. The single-use, disposable sensors do not present the risk of cross-contamination caused by products that are reused from patient to patient. This 510(k) seeks premarket clearance for a line extension model BM-500, compatible with the BM-2070 extension cable and the Nellcor N-395 Pulse Oximeter (a legacy oximeter.). The BM-2070 extension cable was cleared for use with the predicate BMT sensors under K092549.

INDICATION FOR USE:

The OxiprobE is indicated for non-invasive, continuous, beat-by-beat monitoring of oxygen saturation of functional arterial hemoglobin, pulse rate, and pulse amplitude. Individual models are labeled for the intended use. It is for prescription use only.

PREDICATE DEVICE USED FOR SUBSTANTIAL EQUIVALENCE:

Device Feature	Predicate BMT Sensors (K092549)	Subject BMT Sensors (K132516)	Comparison*
Indication for Use	The OxiprobE is indicated for non-invasive, continuous, beat-by-beat monitoring of oxygen saturation of functional arterial hemoglobin, pulse rate, and pulse amplitude. Individual models are labeled for the intended use. It is for prescription use only.	The OxiprobE is indicated for non-invasive, continuous, beat-by-beat monitoring of oxygen saturation of functional arterial hemoglobin, pulse rate, and pulse amplitude. Individual models are labeled for the intended use. It is for prescription use only.	Same
Intended Use	BM-200: Adult / Infant	BM-500: Infant/Adult	Same

510(k) Summary-Continued

Device Feature	Predicate BMT Sensors (K092549)	Subject BMT Sensors (K132516)	Comparison*
	BM-400 Pediatric		
Usage Type	Single Use Disposable	Single Use Disposable	Same
Sterility	Non-Sterile	Non-Sterile	Same
Adhesive Tape Type	BM-200: Tan Woven BM-400 Clear Woven	BM-500: Tan Woven	SE
Emitter – Detector Spacing	BM-200 = 26mm BM-400 = 20mm	BM-500 = 20mm	Same
Tape Length	BM-200 = 110mm BM-400 = 81mm	BM-500 = 80mm	Same
SpO_2 Accuracy (%)	BM-200: 70 - 100 ± 2 BM-400: 70 - 100 ± 3	BM-500 : 70 - 100 ± 3	Same
Pulse Rate Accuracy (bpm)	BM-200: 50 – 150 ± 2 BM-400: 50 – 150 ± 2	BM-500 : 50 – 150 ± 2	Same

PERFORMANCE TESTING:

Nonclinical Bench Testing (No new clinical data was required to support this 510(k)) was included to support substantial equivalence as listed below:

- EN ISO 60601-1:2006, 3rd edition: including
  - Humidity preconditioning treatment (sub-clause 5.7)
  - Accessible parts (sub-clause 5.9.2)
  - Legibility of markings (sub-clause 7.1.2)
  - Durability of markings (sub-clause 7.1.3)
  - Leakage Current Tests (sub-clause 8.7)
  - Temperature test (11.1)
  - Interruption of the power supply (sub-clause 11.8)
  - Power Limitation test (sub-clause 13.1.2)
  - Push test (sub-clause 15.3.2)
  - Drop Test (hand-held) (sub-clause 15.3.4.1
  - With the exception of: Usability EN 60601-1-6, or "accuracy" which was tested elsewhere by the sponsor, and those clauses not applicable to pulse oximetry sensors as determined by the certified testing laboratory
- EN ISO 80601-2-61:2011, Medical electrical equipment Part 2-61 Particular requirements for basic safety and essential performance of pulse oximeter equipment for all units subject of this submission with the exception of those parts which the laboratory determined to be not applicable to sensors.
- Electromagnetic Compatibility and Interference testing (EMC / EMI) was performed on all of the BMT Pulse Oximetry Sensors which are the subject of this 510(k) was conducted to determine compliance with the applicable requirements of the ISO 80601-2-61:2011 Standard as discussed on the FDA's Pulse Oximeter Guidance.
- Pulse and SpO_2 accuracy.

CONCLUSION

It can be concluded from the results that the model BM 500 for use with the Nellcor Model N395 Pulse Oximeter, compatible with the predicate BM-2070 extension cable is substantially equivalent to the predicate.

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

July 30, 2014

BIO Medical Technologies, Co. Ltd.
c/o Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082

Re: K132516
Trade/Device Name: OxiprobE
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 18, 2014
Received: July 21, 2014

Dear Ms. Duncan:

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 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. 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,

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 Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132516

Device Name: OxiprobE

Indications for Use:

The OxiprobE is indicated for non-invasive, continuous, beat-by-beat monitoring of oxygen saturation of functional arterial hemoglobin, pulse rate, and pulse amplitude. Individual models are labeled for the intended use. It is for prescription use only.

Prescription Use ___X___ 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Todd D. Courtney -S
2014.07.30 13:19:01
-04'00'