K092549

Bio Medical Technologies Co.,Ltd
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NOV 16 2009

510(k) Summary

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

Date: August 6, 2009

1. Company and Correspondent making the submission:

	Company
Name	Bio Medical Technologies Co., Ltd.
Address	Megu Bldg. #431-17. Shindang-dong, Jung-gu,Seoul,100-452, Republic of Korea
Phone Fax	+82 2 2234-0780~2 +82 2 2234-0748
Contact	K.N. Kim

2. Device:
   Proprietary Name – OxiprobE
   Common Name – Oximetry Sensor
   Classification Name – Oximeter

3. Predicate Device:
   Model D-25, N-25, D-20, Nellcor Puritan Bennett Inc., K993637
   Philips Reusable SpO2 Sensors-M1191T, M1192T, Philips Medical Systems, K063783

4. Classifications Names & Citations:
   Regulation Number: 21 CFR 870.2700 — Regulation Name: Oximeter
   Regulatory Class: Class II — Product Code: DQA

5. Description:
   The OxiprobE is Pulse Oximetry sensors and cables used for non-invasive measurement of blood oxygen saturation and pulse rate measurement. It consists of Connector, Cable and sensor. Bio Medical Technologies Co., Ltd. supplies both disposable and reusable sensors. 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. Adhesive sensors are patient-dedicated and can travel with your patients. Single-use sensors do not present the risk of cross-contamination caused by products that are reused from patient to patient. Reusable sensors are designed to monitor various sizes of relatively immobile patients. When short-term or intermittent monitoring is necessary, these reusable, non-sterile sensors are an effective monitoring alternative.

The OxiprobE models BM-100, BM-200 and BM-300 are indicated for adult patients.
The OxiprobE model BM-400 is indicated for pediatric patients.
The OxiprobE models BM-300s is indicated for adult patients over 30 kg.
The OxiprobE models BM -600p is indicated for pediatric patients over 10 kg and less than 50 kg.

6. Indication for use:

The OxiprobE is indicated for non-invasive, continuus, beat-by-beat monitoring of oxygen saturation of functional arterial hemoglobin, pulse rate and pulse amplitude. Individual models are labeled specifically for either adult or pediatric use. It is for prescription use only.

7. Review:

The OXIPROBE has the same device characteristics as the predicate device, the intended use, materials, design and use concept are similar.

Based on the comparison of intended use and technical features, the OXIPROBE is substantially equivalent to the predicate device.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Bio Medical Technologies Co., Ltd. concludes that the OXIPROBE are safe and effective and substantially equivalent to predicate devices as described herein.

9. Bio Medical Technologies Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Bio Medical Technologies Company, Limited
C/O Ms. Cathryn Cambria
Arkin Consulting Group, L.L.C.
5536 Trowbridge Drive
Dunwoody, Georgia 30338

NOV 1 6 2009

Re: K092549
Trade/Device Name: OxiprobE
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 6, 2009
Received: August 19, 2009

Dear Ms. Cambria:

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 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

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

Indications for Use

510(k) Number K

Device Name: OxiprobE

Indication for use:

The OxiprobE is indicated for non-invasive, continuus, beat-by-beat monitoring of oxygen saturation of functional arterial hemoglobin, pulse rate and pulse amplitude. Individual models are labeled specifically for either adult or pediatric use. It is for prescription use only.

Prescription Use ✓ OR Over-The-Counter Use
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheis

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

510(k) Number: K092549