SEP 2 2 2009

PHILIPS

K091572

Philips Medizin Systeme Böblingen GmbH

Postfach 1471
71004 Böblingen
Germany

8.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

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This summary was prepared on May 29, 2009.

2. The name of the device is the Philips disposable SpO_2 sensor M1134A. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular 74	§870.2700, II	DQA	Oximeter

3. The modified device is substantially equivalent to previously cleared Philips disposable SpO_2 sensor M1133A (K052377, K063783). The modified device uses adhesive-free material (adhesive-free skins) which covers the optical parts of the sensor and which comes into contact with the patient. Such a modified SpO_2 sensor can be applied to patients whenever skin sensitivity is a concern.

4. The new disposable SpO_2 sensors M1134A are for single use, when continuous non-invasive arterial oxygen saturation and pulse rate monitoring are required.

The measurement method is based on the absorption of light, which is sent through human tissue (for example through the index finger). The light is emitted from two sources with different wavelengths and is received by a photodiode. Through interference with the human tissue the two distinct wavelengths will be differently absorbed. Out of this different absorption behavior a so-called Ratio can be calculated. Based on calibration curves, the Ratio can be related to a SpO_2 value.

5. The modified device has the same intended use as the legally marketed predicate device.

The modified device is indicated for use by health care professionals whenever there is a need for acquiring non-invasively the arterial oxygen saturation to support the measurement of oxygen saturation.

The device is intended for monitoring, recording, and alarming of the physiological parameters arterial oxygen saturation (SpO_2) and pulse rate of adults, infants, and neonates in a healthcare environment and during transport inside and outside of healthcare environments.

6. The modified device has the same technological characteristics as the legally marketed predicate device. Besides the adhesive skins, which cover the optical parts of the predicate device, the modified device uses the identical fundamental principle of measurement, the same type of optical elements and the same type of material. The modification replaces the adhesive parts on the inner side of the predicate device, which comes into contact with the patient, with adhesive-free parts. The purpose of this modification is to have a gentle alternative SpO_2 sensor for patients with fragile skin, such as preterm infants, geriatric and burn patients, in order to help prevent skin trauma.

The modified device is compatible to the same SpO_2 monitors as are the predicate device.

7. The accuracy of the modified device was validated according to ISO 9919. The pulse rate accuracy is not influenced by the modification and therefore the testing for the M1133A is also valid for the M1134A.

8. Because of the minor changes there is no influence on the modified device with regards to technical and clinical performance. To reinforce that the modified device has the same SpO_2 accuracy as the predicate device a desaturation study with a CO-Oximeter as a reference was performed. As recommended by the FDA any tested pulseoximeter-sensor combination should be verified with at least 10 volunteers and at least 20 data samples per volunteer. The modified device was tested with 6 male and six female volunteers in the rage of age 19 to age 39. The skin tone of the subject covered 7 levels from rose beige to dark brown. For the tested combination of pulseoximeter and sensor, more than 300 blood samples were analyzed.

9. Verification, validation and testing activities were conducted to establish the performance and reliability characteristics of the new device. Testing involved system level tests, performance and safety testing from risk and hazard analysis. Clinical validation studies were also conducted. All verification and validation activities were successfully completed.

The results demonstrate that the Philips disposable SpO_2 sensor M1134A meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 22 2009

Dr. Jens-Peter Seher
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Re: K091572
Trade/Device Name: Philips Disposable SpO_2 Sensors M1134A
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 31, 2009
Received: August 7, 2009

Dear Dr. Seher:

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

Indications for Use

510(k) Number (if known): K091572

Device Name: Philips disposable SpO_2 sensors M1134A

Indications for Use: The Philips disposable SpO_2 sensor M1134A is indicated for use by health care professionals whenever there is a need for acquiring non-invasively the arterial oxygen saturation to support the measurement of oxygen saturation. Intended for monitoring, recording, and alarming of the physiological parameters arterial oxygen saturation (SpO_2) and pulse rate of adults, infants, and neonates in a healthcare environment and during transport inside and outside of healthcare environments.

Prescription Use yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schulteis

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

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