K042306

OCT 15 2004

SECTION 9.0

510(k) SUMMARY

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510(k) Summary
(As required by 21 C.F.R. §807.92)

Submitted by:	Egon Pfeil Philips Medizin Systeme Boeblingen GmbH Cardiac and Monitoring Systems Hewlett-Packard Str.2 71034 Boeblingen Germany
Date of Summary:	August 20, 2004
Device Name	The Philips Disposable SpO_2 Sensor M1131A.
Common Name	SpO_2 Sensor
Classification Name	Classification Name: Oximeter (DQA) Regulation Number: 21 C.F.R §870.2700
Predicate Devices	Philips M1191T, M1192T reusable SpO_2 sensors, and M1903B (Nellcor/Tyco Oxisensor II™ D-20)and M1904B (Nellcor/Tyco Oxisensor II™ D-25) disposable SpO_2 sensors cleared pursuant to K882609, 1/19/89; K990972, 4/19/99, K000822, 4/6/00, and K032979/S2, 2/20/04.
Device Description	The Philips SpO_2 devices measure, non-invasively, the arterial oxygen saturation of blood. The measurement method is based on the red and infrared light absorption of hemoglobin and oxyhemoglobin. Light of a red and infrared light source is emitted through human tissue and received by a photodiode. The measurement is based on the absorption of light, which is emitted through human tissue (for example through the index finger). The light comes from two sources (red LED and infrared LED) with different wavelengths and is received by a photodiode. Out of the different absorption behavior of the red and infrared light a so-called Ratio can be calculated. The saturation value is defined by the percentage ratio of the oxygenated hemoglobin [HbO_2] to the total amount of hemoglobin [Hb]. $$SpO_2 = [HbO_2] / ([Hb] + [HbO_2])$$ Out of calibration curves, which are based on controlled hypoxia studies with healthy non-smoking adult volunteers over a specified saturation range (SaO_2 from 100%-70%), the

	Ratio can be related to a SpO_2 value. The devices contain a red and infrared light source and a photodiode receiving the non-absorbed red and infrared light. The received signals are forwarded to a measurement device that amplifies the acquired signal and an algorithm that calculates the ratio and converts via a validated calibration table the ratio to a saturation value.
Intended Use	The Philips Reusable SpO_2 Sensors are intended for acquiring non-invasively the arterial oxygen saturation to support the measurement of oxygen saturation and pulse rate. M1131A is indicated for adult and pediatric patients.
Technological characteristics	The Philips Disposable SpO_2 Sensor has the same technological characteristics as the legally marketed predicate device.
Testing	Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the new device. Testing involved environmental, safety testing from hazard analysis, interference testing, and clinical evaluations for accuracy. Hardware verification testing was also conducted. Pass/Fail criteria were based on standards, where applicable, and on the specifications cleared for the predicate device. Test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

Mr. Egon Pfeil
Regulatory Affairs Engineer
Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard-Str. 2,
71034 Böblingen
GERMANY

Re: K042306
Trade/Device Name: The Philips Disposable SpO_2 Sensor M1131A
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 20, 2004
Received: August 25, 2004

Dear Mr. Pfeil:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Chiu Lin, Ph.D.
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): _____
Device Name: The Philips Disposable SpO_2 Sensor M1131A

Indications for Use: The Philips disposable SpO_2 Sensor is intended for non-invasive measurement of oxygen saturation (SpO_2) and pulse rate.

Indicated for adult/pediatric patients.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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