K062455

PHILIPS Medical Systems

NOV - 3 2006

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

Submitted by:	Philips Medical Systems, Inc. Ultrasound and Monitoring Division / Patient Monitoring Supplies 3000 Minuteman Road Andover, MA 01810
Company Contact:	Mr. Rich McCleary Senior Manager of Quality and Regulatory Affairs Tel: (978) 659-4914
Date of Summary:	August 18, 2006
Device Name	Philips Reusable SpO_2 Sensor, Models M1191B, M1191BL and M1191BNL
Common Name	SpO_2 pulse oximeter sensor
Classification Name	Classification Name: Oximeter Regulation Number: 21 C.F.R §870.2700
Predicate Device	Philips Medical System Adult SpO2 sensor, model # M1191A Cleared for marketing via FD&C Act §510(k)# K882609, K990972, K000822 and K030973.
Modifications	The modification involves changes to the exterior cuff materials to improve quality, enhance value and accommodate patients with larger fingers.

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

Philips reusable SpO2 sensors are for multi-patient use, when continuous non-invasive arterial oxygen saturation and pulse rate monitoring are required.

M1191B, M1191BL and M1191BNL sensors are indicated for use with adult patients.

Technological characteristics

The Philips Reusable SpO_2 Sensors have the same technological characteristics as the legally marketed predicate devices.

Testing

Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the modified device.

Testing involved environmental and clinical evaluations for accuracy. Hardware verification testing and cable interface verification testing were also conducted. Design verification and validation test results confirmed that the device is substantially equivalent with the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

Mr. Rich McCleary
Senior Manager, Quality & Regulatory Affairs
Phillips Medical Systems
3000 Minuteman Road
Andover, Massachusetts 01810-1099

Re: K062455
Trade/Device Name: Philips Reusable $Sp0_2$ Sensors Models, M1191B, M1191BL and M1191BNL
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: October 2, 2006
Received: October 4, 2006

Dear Mr. McCleary:

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

Sincerely yours,

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): **K062455**

Device Name: Philips Reusable SpO_2 Sensors
Models M1191B, M1191BL and M1191BNL

Indications For Use: Philips reusable SpO_2 sensors are for multi-patient use, when continuous non-invasive arterial oxygen saturation and pulse rate monitoring are required.

Prescription Use ✓ 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)

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

510(k) Number: K062455