

NOV - 9 2006

Special 510(k) Premarket Notification
SpO2 Pulse Oximeter Sensor - Model Nos. M1196A and M1196T

K062605

PHILIPS Medical Systems

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 01810-1099

Company Contact: Mr. Rich McCleary
Senior Manager of Quality and Regulatory Affairs
Tel: (978) 659-4914

Date of Summary: August 31, 2006

Device Name Philips Reusable SpO₂ Sensor,
Models M1196A and M1196T

Common Name SpO₂ 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, K030973 and K032979.

Modifications The modification involves a change from a soft cuff style to a clip
style housing design to facilitate attachment and removal from a
patient's finger.

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Device Description

The Philips SpO₂ 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 [HbO₂] 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 (SaO₂ from 100%-70%), the Ratio can be related to a SpO₂ 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 M1196A and M1196T reusable Clip sensors provide continuous, non-invasive measurement of arterial oxygen saturation (pulse rate signal and plethysmograph wave) to any SpO₂ device that has passed validation testing. Either sensor can be comfortably clipped onto the finger of patients weighing > 40 kg (typically adult patients).

Technological characteristics

The Philips Reusable SpO₂ 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Rich McCleary
Senior Manager of Quality and Regulatory Affairs
Philips Medical Systems, Incorporated
Ultrasound and Monitoring Division/Patient Monitoring Supplies
3000 Minuteman Road
Andover, Massachusetts 01810-1099

Re: K062605

Trade/Device Name: Philips SpO₂ Reusable Clip Sensors Models M1196A
and M1196T

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: II

Product Code: DQA

Dated: October 10, 2006

Received: October 11, 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): **K062605**

Device Name: Philips SpO₂ Reusable Clip Sensors
Models M1196A and M1196T

Indications For Use: The M1196A and M1196T reusable Clip sensors provide continuous, non-invasive measurement of arterial oxygen saturation (pulse rate signal and plethysmograph wave) to any SpO₂ device that has passed validation testing. Either sensor can be comfortably clipped onto the finger of patients weighing > 40 kg (typically adult patients).

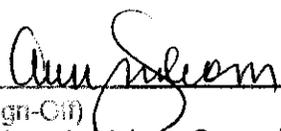
Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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)


Ann Sullivan
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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