8.0 510(k) Summary

K062268

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:

   Philips Medical Systems

   OCT 18 2006

   This summary was prepared on 4 August, 2006.

2. The name of this device is the Masimo SET SpO_2 module for Philips and M3001A Multi-measurement Server option A03. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Anesthesiology 73	§868.2375, II	BZQ	Monitor, Breathing Frequency
	§870.2700, II	DQA	Oximeter

3. The new device is substantially equivalent to previously cleared Philips devices M3001A marketed pursuant to K013199, K020531, K030973 and K040259 as well as the Masimo SET SpO_2 plug-in module and and MS-13 Board pursuant to K040259, K053269 and K051439.

4. The modification creates the Masimo SET SpO_2 pulse oximetry module for use in Philips host patient monitors.

5. The new device has the same Indications for Use as the legally marketed predicate device: indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics and neonates in patient transport and healthcare environments.

6. The new device has the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, integration tests, environmental tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that the pulse oximetry module functionality meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2006

Philips Medical Systems North America Company
C/O Mr. Dave Osborn
Programs Manager
Philips Medical System
3000 Minuteman Road
Andover, Massachusetts 01810

Re: K062268
Trade/Device Name: Masimo SET SpO_2 Module for Philips and M3001A Multimeasurement Server Option A03
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 22, 2006
Received: September 26, 2006

Dear Mr. Osborn:

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.

Food and Drug Administration
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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/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): K062268

Device Name: Masimo SET SpO_2 module for Philips and M3001A Multi-measurement Server option A03

Indications for Use:

Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics and neonates in patient transport and 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K062268