K090360

MAY - 4 2009

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:

Dr. Jens-Peter Seher
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This summary was prepared on February 09, 2009.

2. The name of this device is the Philips M3001A Multi Measurement Server with Nellcor OxiMax SpO_2 measurement module.

Classification names are as follows:

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

3. 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 adult, pediatric and neonatal patients in a hospital environment and during transport inside and outside of hospital environment.

4. The modified device Philips M3001A Multi Measurement Server is substantially equivalent to the legally marketed M3001A Multi Measurement Server (K030973, K033715). The modification consists of the integration of the Nellcor OxiMax SpO_2 measurement module which is substantially equivalent to the legally marketed Nellcor OxiMax N-600x Pulse Oximeter (K060576).

5. The modification adds to the M3001A Multi Measurement Server the Nellcor OxiMax SpO_2 measurement module as an option in order to use the full Nellcor OxiMax technology.

6. The modified device has the same intended use as the legally marketed predicate device. The device is intended for monitoring, transport monitoring, recording, and alarming of multiple physiological parameters of adult, pediatric and neonatal patients in a hospital environment and during transport inside and outside of hospital environment by health care professionals.

7. The SpO_2 measurement is based on the absorption of light, which is transmitted through human tissue (e.g. index finger). Two light sources transmit red and infrared light through the human tissue.

The ratio of the different absorption of the red and infrared light is 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 the specified saturation ranges, the ratio determines the SpO_2 value. The measurement accuracy of SpO_2 in the specified ranges is between 2% and 4% RMS dependent on the Nellcor OxiMax sensor type. The measurement accuracy of pulse rate in the range of 25 bpm to 250 bpm is ±3 bpm.

8. The modification is the integration of the Nellcor OxiMax SpO_2 measurement module into the M3001A with minor hardware and software adaptations. The modification leads to a compact Multi measurement Server with integrated full Nellcor OxiMax technology.

9. The accuracy of the device was validated according to ISO 9919:2005.

10. 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

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Dr. Jens-Peter Seher
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GERMANY

Re: K090360
Trade/Device Name: Philips M3001A Multi Measurement Server
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ
Dated: April 6, 2009
Received: April 9, 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting 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: Philips M3001A Multi Measurement Server

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 adult, pediatric and neonatal patients in a hospital environment and during transport inside and outside of hospital environment.

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)

5/4/09

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

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