K081870

510(k) Summary of Safety and Effectiveness

JUL 31 2008

Date: June 30, 2008

Submitter: GE Healthcare Finland Oy.
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Device Trade Name: Masimo Compatible Saturation Module, E-MASIMO

Common /Usual Name: Pulse Oximeter

Classification Names: 21 CFR 870.2700 Oximeter (DQA)

21 CFR 870.2710 Ear Oximeter (DPZ)

Predicate Devices: **K052755** Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT and accessories

Device Description: The Masimo Compatible Saturation Module, E-MASIMO, is a single-width plug-in parameter module for a S/5 Modular Monitoring system. The Masimo Compatible Saturation Module, E-MASIMO is used for measuring noninvasive arterial oxygen saturation (SpO2) and pulse rate of hospitalized patients.

The SpO2 measurement is based on light transillumination and is made optically with an infrared light and a red light sources and a photosensitive detector. The SpO2 value and pulse rate are calculated based on the signals, which are measured with the photosensitive detector in the SpO2 sensor.

The Masimo Compatible Saturation Module, E-MASIMO consists of an electronic measurement board based on MasimoSET® technology (OEM from Masimo Inc.), an interface board and connector flex board designed by GE Healthcare Finland Oy (former Datex-Ohmeda Div) for connecting the Masimo measurement board to a Datex-Ohmeda S/5 modular monitor.

The Masimo Compatible Saturation Module, E-MASIMO was designed to work with the GE Healthcare modular monitoring platforms. Currently it can be used in the following four monitor platforms:

- GE Datex-Ohmeda S/5* Anesthesia Monitor
- GE Datex-Ohmeda S/5* Compact Anesthesia Monitor
- GE Datex-Ohmeda S/5* Critical Care Monitor
- GE Datex-Ohmeda S/5* Compact Critical Care Monitor

*Note: GE Datex-Ohmeda S/5 is the brand name. The older versions of S/5 monitor platforms were designated AS/3 for anesthesia models and CS/3 for critical care models instead of the current designator S/5, and can also use the Masimo Compatible Saturation Module, E-MASIMO.

The Masimo Compatible Saturation Module, E-MASIMO is compatible with the above monitors that run software versions:

- S-STD94 or S-ARK94 or newer
- S-ANE97 or newer
- S-ICU97 or newer

Note: For reference the latest 510(k) clearances of the above listed monitors/software are as follows

- Datex-Ohmeda S/5 Anesthesia Monitor with L-ANE05 AND L-ANE05A with 8-module monitor frame F-CU8 or the 5-module monitor frame F-CU5(P): **K051400**
- Datex-Ohmeda S/5 Compact Anesthesia Monitor with L-CANE05 and L-CANE05A Software with frame F-CM1: **K061185**
- Datex-Ohmeda S/5 Compact Critical Care Monitor with L-CICU05 and L-CICU05A with frame F-CMC1: **K071020**
- Datex-Ohmeda S/5 Critical Care Monitor with L-ICU05 and L-ICU05A software, with 8-module monitor frame F-CU8 or the 5-module monitor frame F-CU5(P) : **K071889**

The Masimo Compatible Saturation Module, E-MASIMO uses Masimo SpO2 accessories including interconnect cable 2027263-002 (manufactured by Masimo Inc. and distributed by GE Healthcare) and interconnect cables 2017002-001, and 2017002-003 manufactured by GE Healthcare *Information Technologies*. All accessories have been

previously cleared. See Section 6.7, Table 3.

Indications for Use:

The Masimo Compatible Saturation Module, E-MASIMO, and accessories are indicated for monitoring arterial oxygen saturation and pulse rate of hospitalized patients. The device is indicated for use by qualified medical personnel only.

Technology:

The Masimo Compatible Saturation Module, E-MASIMO employs the same functional scientific technology as its predicate device.

Test Summary:

The subject of this 510(k) is a modification for the Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT. The Masimo Compatible Saturation Module, E-MASIMO complies with the voluntary standards as detailed in Section *4.2 Specific Standards and Guidance* of this submission. The following quality assurance measures were applied to the development of the Masimo Compatible Saturation Module, E-MASIMO:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Subsystem Verification
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these tests and analysis demonstrated that the Masimo Compatible Saturation Module, E-MASIMO is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GE Healthcare Finland Oy
C/O Mr. John Pendergast
Regulatory Affairs Specialist
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

JUL 31 2008

Re: K081870
Trade/Device Name: Masimo Compatible Saturation Module, E-MASIMO and Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 30, 2008
Received: July 1, 2008

Dear Mr. Pendergast:

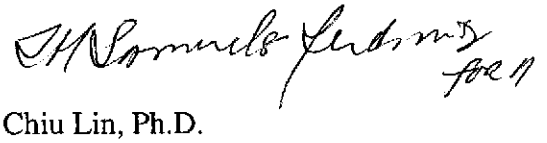
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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):

Device Name: Masimo Compatible Saturation Module, E-MASIMO and accessories

Indications for Use:

The Masimo Compatible Saturation Module, E-MASIMO, and accessories are indicated for monitoring arterial oxygen saturation and pulse rate of hospitalized patients. The device is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (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)

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

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