510(k) SUMMARY
K 123043

OCT 2 5 2012

1. 510(k) Owner Name and Address:
   PHASEIN AB
   Svärdvägen 15
   182 33 Danderyd
   Sweden
   Telephone: 46-8-544-98-150
   Fax: 46-8-544-98-169
   PHASEIN is a subsidiary of Masimo Corporation

2. Contact Person:
   David Weissburg
   Weissburg Associates
   808 Williamson St., Suite 402
   Madison, Wisconsin, 53703 USA

3. Date prepared: 28 September, 2012

4. Trade Name: Infrared Mainstream Gas Analyzer (IRMA), model/catalogue numbers 200101 and 200601

5. Common Name: Multigas Monitor

6. Classification Names: Carbon-dioxide gas analyzer (21 CFR 868.1400, Product Code CCK)

7. Substantially equivalent to:

   ISA (Infrared Sidestream Gas Analyzer, K103604)
   VEO Multigas Monitor for Pocket PC (K081601)

8. Device Description: IRMA is a mainstream respiratory gas analyzer based on infrared gas spectrometry. It is intended to be connected to another medical backboard device for display of respiratory parameters. IRMA is connected to the patient breathing circuit via the Airway Adapter. This premarket submission adds the M80 device as a host backboard display to IRMA. There are no changes to the previously cleared sensor technology.

   The following IRMA models are available:

a) IRMA CO2 (model/catalogue number 200101), measurement of CO_2.

b) IRMA AX+ (model/catalogue number 200601), measurement of CO_2, N_2O and 5 anesthetic agents with automatic agent identification

   The IRMA product family also includes the adult and pediatric/infant Airway Adapter. A modura holder and velcro holder are offered as optional accessories.

9. Indications for Use:

The IRMA mainstream gas analyzer is intended to be connected to other medical devices for monitoring of breath rate and the breathing gases CO2, N2O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.

It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit and patient room for adult, pediatric and infant patients. IRMA CO2 may also be used in the emergency medical services environment and road ambulances.

Note: An IRMA mainstream gas analyzer shall only be connected to medical backboard devices approved by PHASEIN.

10. Comparison to predicates: The IRMA model/catalogue numbers 200101 and 200601 have the same gas measurement capabilities as its predicate devices. The IRMA uses the same basic technology concepts used in the predicate devices. The intended use of the IRMA and its predicates are the same. All the devices consume equivalent amounts of electric power and utilize single-patient-use connections to interface with gases in the breathing circuit. Labeling and materials used are equivalent.

11. Testing vs. predicates: Testing in direct comparison to predicates throughout the operating range was conducted using calibrated gas samples and legally marketed anesthesia and ventilation devices.

12. Conclusions from testing: The IRMA, models 200101 and 200601 demonstrated performance, safety and effectiveness equivalent or superior to its predicates in all characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 25 2012

Phasein AB
C/O Weissburg Associates
Mr. David Weissburg
Principal
808 Williamson Street, Suite 402
Madison, Wisconsin 53703

Re: K123043
Trade/Device Name: IRMA – Infrared Mainstream Gas Analyzer
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK, CBR, CBS, CBQ, NHQ, NHP, NHO
Dated: September 19, 2012
Received: September 28, 2012

Dear Mr. Weissburg:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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 Statement

510(k) Number: K123043

Device Name:
IRMA – Infrared Mainstream Gas Analyzer.

Indications for Use:

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It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit and patient room for adult, pediatric and infant patients. IRMA CO2 may also be used in the emergency medical services environment and road ambulances.

Note: An IRMA mainstream gas analyzer shall only be connected to medical backboard devices approved by PHASEIN.

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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