SEP 15 2005

K051857

# 510(k) SUMMARY

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

2. Contact Person:
   David Weissburg
   Weissburg Associates
   Madison, Wisconsin
   Telephone: 1-608-770-0223

3. Date: 6 September 2005
4. Trade Name: VEO Multigas Monitor for Pocket PC
5. Common Name: Multigas Monitor

6. Classification Names:
   a. Carbon dioxide gas analyzer (21 CFR 868.1400, Product Code CCK)
   b. Oxygen gas analyzer (21 CFR 868.1720, Product Code CCL)

7. Substantially equivalent to:
   a. Tidal Wave Model 610, Novametrix Medical Systems Inc. (K963327)
   b. MX300 Portable Oxygen Monitor, Teledyne Analytical Instruments (K024155)
   c. S/5 Multigas Monitor, Datex-Ohmeda-GE (K051092)
   d. Handi, Ceramatec, Inc (K973282)

8. Device description: The VEO Multigas Monitor for Pocket PC combines a miniature mainstream infrared gas analysis bench with an ultra-fast response oxygen fuel cell. The complete multigas analyzer is contained within a transducer that is attached to the breathing circuit via an airway adapter.

9. Intended Use: The VEO Multigas Monitor for Pocket PC is intended to provide monitoring of carbon dioxide and oxygen during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, and emergency medicine settings for adult and pediatric patients.

10. Comparison to predicates: The VEO Multigas Monitor for Pocket PC combines the gas monitoring capabilities of two predicate devices into one device. The VEO Multigas Monitor for Pocket PC uses the same basic technology concepts used in the predicate devices, while adding improvements derived from advanced electronics and miniaturization. The intended uses of the VEO Multigas Monitor for Pocket PC and its predicates are the same. All the devices consume equivalent amounts of electric power and utilize disposable single-patient-use airway adapters to interface with gases in the breathing circuit. Labeling and materials used are equivalent, except that the VEO Multigas Monitor for Pocket PC displays numeric and graphic information on an off-the-shelf Pocket PC. PHASEIN-approved Pocket PCs have been tested and validated as reliable components of the VEO Multigas Monitor device.

11. Testing vs. predicates: Non-clinical 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 VEO Multigas Monitor for Pocket PC demonstrated performance, safety and effectiveness equivalent or superior to its predicates in all characteristics. The VEO Multigas Monitor for Pocket PC demonstrated superior performance in response time, accuracy, precision, and reliability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2005

Phasein AB
C/O Mr. David Weissburg
Weissburg Associates
4213 Winnequah Drive
Madison, Wisconsin 53716

Re: K051857
Trade/Device Name: VEO Multigas Monitor For Pocket PC, Model 400221
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon dioxide gas analyzer
Regulatory Class: II
Product Code: CCK, CCL
Dated: June 30, 2005
Received: July 8, 2005

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.

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-. 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: _____

Device Name: VEO Multigas Monitor for Pocket PC
Indications for Use:

The VEO Multigas Monitor for Pocket PC is intended to provide monitoring of carbon dioxide and oxygen during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room and emergency medicine settings for adult and pediatric patients.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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