# 510(k) SUMMARY, K 072813 page 1 of 2

1. 510(k) Owner Name and Address:
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   Sweden
   Telephone: 46-8-544-98-150
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2. Contact Person:
   David Weissburg
   Weissburg Associates
   Madison, Wisconsin, USA
   Telephone: 1-608-770-0223

3. Date: September 24, 2007

4. Trade Name: EMMA Emergency Capnometer

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5. Common Name: Carbon Dioxide Gas Analyzer

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

7. Substantially equivalent to:
   a. Tidal Wave Model 610, Novametrix Medical Systems Inc. (K963327)
   b. EMMA Emergency Capnometer, Phasein AB. (K063167)

8. Device description: The EMMA Emergency Capnometer is a miniature mainstream infrared gas analysis bench with an integrated user interface. The complete carbon dioxide analyzer is contained within a transducer that is attached to the breathing circuit via the EMMA Airway Adapter.

9. Intended Use:
   The EMMA Emergency Capnometer Monitor measures, displays and monitors carbon dioxide concentration and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients.

   The EMMA Emergency Capnometer Analyzer measures and displays carbon dioxide concentration and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients.

10. Comparison to predicates: The EMMA Emergency Capnometer combines carbon dioxide measurement capabilities and enhanced portability. The EMMA Emergency Capnometer device is identical to its precursor (K063167), but with an extended indication for use that includes infant patients and the addition of the infant-specific EMMA Airway Adapter Infant, which is required when monitoring infants. The intended use of the EMMA Emergency Capnometer is equivalent to the predicate Tidal Wave Model 610 (K963327). Both devices utilize disposable single-patient-use airway adapters 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 EMMA Emergency Capnometer 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
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2007

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

Re: K072813
Trade/Device Name: EMMA Emergency Capnometer
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: September 25, 2007
Received: October 1, 2007

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) 276-0120. 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: K072813

Device Name: EMMA Emergency Capnometer

Indications for Use:

The EMMA Emergency Capnometer Monitor measures, displays and monitors carbon dioxide concentration and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients.

The EMMA Emergency Capnometer Analyzer measures and displays carbon dioxide concentration and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant 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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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072813