K974805

MAR 11 1998

natus®

510(k) Summary

This summary of safety and effectiveness is provided in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR § 807.92(c).

1. **Manufacturer's Information**

Manufacturer's Information	Contact Person	Phone & Fax Numbers
Natus Medical, Inc. 1501 Industrial Road San Carlos, CA 94070-4111	Esther Kadash Director, Regulatory Affairs	(650) 802-0400 (650) 802-0531 (fax) (650) 802-0401 (alt. fax)

Summary prepared on December 22, 1997

2. **Device Name and Classification Information**

Device Trade or Proprietary Name	CO-STAT™ End Tidal Breath Analyzer
Common, Usual, or Classification Name	Common: Breath analyzer Classification: Carbon monoxide gas analyzer
Classification	Carbon monoxide gas analyzer – 21 CFR § 868.1430 Class II
Product Code	CCJ

3. **Marketed Devices to which the Natus Breath Analyzer is substantially equivalent.**

Manufacturer	Common name	Device Class	Classification Panel	Product Code	K#
Vitalograph	Carbon monoxide gas analyzer	II	Anesthesiology	73 CCJ	K902113A
Pryon	Carbon dioxide gas analyzer	II	Anesthesiology	73 CCK	K935272
Iadec	Carboxyhemoglobin assay	II	Hematology	GHS	K770209

Table 2: Predicate Devices

4. **Device Intended Use**

The Natus Breath Analyzer is intended for non-invasive measurement of respiratory rate, end tidal carbon dioxide concentration, and end tidal carbon monoxide (corrected for background carbon monoxide) concentration in the breath. Respiratory rate and end tidal carbon dioxide provide an indication of respiratory status; end tidal carbon monoxide is used for the detection and identification of levels of carboxyhemoglobin (COHb). Elevated levels of COHb may be due to environmental exposure or an increased rate of hemolysis; normal levels of COHb may indicate a normal rate (i.e., the absence of an elevated rate) of hemolysis.

5. **Device Description**

The Natus Breath Analyzer is indicated for use with neonates, children, and adults breathing spontaneously. The analyzer measures the carbon monoxide concentration in end tidal breath, as an indicator of the blood level of COHb. The level of COHb (and consequently the concentration of carbon monoxide in the end tidal breath) can be affected by endogenous sources (for example hemolysis), exogenous sources (for example, combustion engine exhaust), or in some cases both. The analyzer is also indicated for use in respiratory status evaluation, whenever measurements of

respiratory rate and end tidal carbon dioxide concentration are desired. The analyzer is indicated for use under the direction of a physician in hospitals and a variety of health care settings.

The Natus Breath Analyzer system is a point-of-care test that consists of the instrument and a single-use patient sampler. The patient sampler incorporates a flexible nasal catheter with a filter cartridge that attaches to the device. An integral adhesive strip on the catheter aids in proper placement in the nostril.

The computer-controlled instrument contains two gas analysis sensors: an infra-red carbon dioxide sensor and an electrochemical carbon monoxide sensor. The signal produced by the carbon dioxide sensor is analyzed to determine the end tidal carbon dioxide concentration and the respiratory rate. The signal produced by the carbon monoxide sensor is analyzed to determine the average carbon monoxide concentration. The end tidal carbon monoxide concentration is calculated by an algorithm using carbon monoxide and carbon dioxide concentrations.

During the automated test procedure the device displays appropriate prompts. The user operates the instrument by selecting menu options from the display screen. During sampling, a small volume of the patient's breath is continuously drawn into the instrument for a short time. Results are displayed and printed at the end of the test.

6. Summary of Technological characteristics compared to marketed devices.

The Natus Breath Analyzer utilizes the same respiratory gas concentration measurement technology as the predicate devices.

Technology	Natus Breath Analyzer	Vitalograph BreathCO monitor	Iadec Ecolyzer carboximeter	Pryon SC-210 CO_2 monitor
Electrochemical fuel cell to measure carbon monoxide	Yes	Yes	Yes	N/A
Infrared technology to measure carbon dioxide	Yes	N/A	N/A	Yes
End-tidal measurements	Yes	Yes	Yes	Yes
Measures ambient carbon monoxide	Yes	Yes	Yes	N/A
Non-continuous single test	Yes	Yes	Yes	Yes ‡
Sidestream sample method	Yes	No	No	Yes
Method of defining end-tidal carbon monoxide	Derived from CO_2 waveform and average CO output	Voluntary breathing maneuver	Voluntary breathing maneuver	N/A

Table 3: Technology Comparisons with Predicate Devices

‡ Pryon device can also be used in continuous monitoring mode.

Materials are shown appropriate for use based on testing. There are no known biocompatibility or toxicology issues.

7. Summary of Non-Clinical Tests

Non-clinical tests performed on a breathing simulator demonstrated that the device can accurately measure end tidal carbon monoxide, end tidal carbon dioxide, and respiratory rate for a wide range of breath parameters (breath rate, tidal volume, gas concentrations, I:E ratio,), including values expected from the neonatal population.

8. Summary of Clinical Tests

A clinical study was performed to compare the carbon monoxide, carbon dioxide, and respiratory rate measurement performance of the Natus Breath Analyzer with the predicate devices (Vitalograph and Pryon). This study was performed on adult, pediatric, and neonatal subjects at three clinical sites. The study demonstrated that device performance is substantially equivalent to the predicate devices.

9. Conclusions from Testing

Testing results demonstrated no significant difference between the Natus Breath Analyzer and the predicate devices in adult and pediatric populations for all three measurements (respiratory rate, end tidal carbon monoxide, and carbon dioxide), and demonstrated no significant difference for carbon dioxide and respiratory rate measurements in the neonatal population. The neonatal population was not tested for carbon monoxide with the predicate device because this population is unable to perform the voluntary breathing maneuver required for the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 11 1998

Esther Kadash
Director of Regulatory Affairs
Natus Medical Inc.
1501 Industrial Road
San Carlos, California 94070-4111

Re: K974805
CO-STAT™ End Tidal Breath Analyzer
Regulatory Class: II
Product Code: GHS, CCK, CCJ
Dated: December 22, 1997
Received: January 5, 1998

Dear Ms. Kadash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

natus®

Indications for Use

510(k) Number (if known): K974805

Device Name: Natus Breath Analyzer

Indications for Use:
The Natus Breath Analyzer is intended for non-invasive, quantitative measurement of respiratory rate, end tidal carbon dioxide concentration, and end tidal carbon monoxide (corrected for background carbon monoxide) concentration in the breath. The analyzer is intended for use with neonates, children, and adults breathing spontaneously.

The analyzer measures the carbon monoxide concentration in end tidal breath, as an indicator of the blood level of COHb. The level of COHb (and consequently the concentration of carbon monoxide in the end tidal breath) can be affected by endogenous sources (for example the rate of hemolysis), exogenous sources (for example, combustion engine exhaust), or in some cases both. The COHb level, elevated or normal, can be used in the diagnosis of medical conditions in which the rate of hemolysis may be relevant, and in the monitoring of patient populations affected by the rate of hemolysis. The analyzer is also indicated for use in respiratory status evaluation, whenever measurements of respiratory rate and end tidal carbon dioxide concentration are desired.

The analyzer is intended for use under the direction of a physician in hospitals and a variety of health care settings.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 974805

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)