K083056
P. 1 of 3

510(k) Summary
Page 1 of 3
11-Feb-09

FEB 23 2009

Mercury Medical, Inc.
11300 - 49th St. North
Clearwater, FL 33762-4800

Tel – (727) 573-0088
Fax – (727) 571-3922

Official Contact: Jeff Ratner – VP Engineering and Quality Assurance

Proprietary or Trade Name: Neo-StatCO_2 <Kg

Common/Usual Name: CO_2 detector

Classification Name/Code: CCK – carbon dioxide gas analyzer

Device: Neo-StatCO_2<Kg

Predicate Devices: Mercury Medical - Mini-StatCO_2 – K031411
Nellcor – Pedi-CAP™ - K944400
Oridion – MicroCap – K024300

Device Description:
Neo-StatCO_2 <Kg is a colorimetric breath indicator for visualization of exhaled CO_2. It is designed to connect between an endotracheal tube and a breathing device to help verify proper intubation. Exhaled gas passes through the indicator to detect approximate ranges of end-tidal CO_2 by color comparison. Color change is rapid and the detector has the ability to show color changes with 1 ml tidal volume and up to a respiratory rate of 100 breaths per minute. The detector may be used during patient transport or in locations when intubations are performed. While the indicator functions at relative humidity (RH) of up to 100%, it is not recommended for use below 10% RH. It may be used for up to 24 hours.

Use only ET tubes and connectors and gas source devices, i.e. manual resuscitators and ventilators, which are intended for use with neonates and infants.

Indications for Use:
The Neo-StatCO_2 <Kg is indicated to provide a semi-quantitative visualization of the CO_2 in the patient airway. It is an adjunct in patient assessment to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician. Intended for use with neonate and infant patients from 250g to 6 kg.

Patient Population: Neonate and infant - 250 g to 6 Kg

Environment of Use: Hospital, sub-acute facilities, pre-hospital and transport

K083057
p. 2 of 3

510(k) Summary
Page 2 of 3
11-Feb-09

Summary of substantial equivalence

	Predicate **Mini-StatCO$_2$™** **K031411** **Or other predicates as indicated**	**New Model** **Neo-StatCO$_2$<Kg™**
Indications for Use	The Mini-StaCO$_2$ is indicated to provide a semi-quantitative visualization of the CO_2 in the patient airway. It is an adjunct in patient assessment to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician.	Same as predicate device
Environment of use	Hospital, sub-acute facilities, pre-hospital and transport	Same as predicate
Patient Population	Neonate and pediatric **Oridion MicroCap – K024300** Indications as listed in 510(k) Summary and Instructions for Use: Include "The monitor is intended for use on adult, pediatric, and infant/neonatal patients."	Neonate and infant (250g to 6 kg)
Physical and Performance Characteristics		
Weight	5 g	3 g
Internal volume	3 cc	1 cc
Resistance to flow	1.23 cm H_2O @ 10 Lpm 8.8 cm H_2O @ 30 Lpm	1.86 cm H_2O @ 10 Lpm 15.6 cm H_2O @ 30 Lpm
Duration of CO_2 detection	Up to 24 hours	Up to 24 hours
Effectiveness of color change for the intended population		Performance testing to demonstrate ability of indicator to change color for the intended body weight, tidal volume and breath rate under conditions of use

510(k) Summary
Page 3 of 3
11-Feb-09

	Predicate **Mini-StatCO$_2$™** **K031411** **Or other predicates as indicated**	**New Model** **Neo-StatCO$_2$ <Kg™**
Operating Conditions	Operating range – -10°C to +50°C	Operating range – -10°C to +50°C
Storage Conditions	Color change function after storage at 0°C and 60°C	Color change function after storage at 0°C and 60°C
Contraindications and Warnings		
Contraindications and Warnings	Do not use for detection of hypercapnia Do not use for the detection of main-stem bronchial intubation Do not use during mouth to tube ventilation Do not use the CO_2 detector to detect oropharyngeal tube placement Standard clinical assessment must be used	Same

The Neo-StatCO$_2$ <Kg™ is viewed as substantially equivalent to the predicate device because:

Indications –
- Identical to predicate – Mercury Mini-StatCO$_2$™ - K031411

Patient Population –
- Expanded from predicate – Mercury Mini-StatCO$_2$™ - K031411
- Similar to – Oridion MicroCap – K024300

Technology –
- Chemical indicator technology for detection of the presence of CO_2 – Mercury Mini-StatCO$_2$™ - K031411

Materials –
- The materials in patient contact are identical to predicate devices

Environment of Use –
- Identical to predicate – Mercury Mini-StatCO$_2$™ - K031411

Differences –
The only difference between the Mercury Mini-Stat CO_2 is the expansion of the patient population to include patients with a body weight of 250 g to 6 Kg which we have demonstrated as being effective via comparative bench testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mercury Medical
C/o Mr. Paul Dryden
Promedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

FEB 23 2009

Re: K083056
Trade/Device Name: Neo-StatCO_2<Kg
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: February 11, 2009
Received: February 12, 2009

Dear Mr. Dryden:

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,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting 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: K083056

Device Name: Neo-StatCO_2 <Kg

Indications for Use:

The Neo-StatCO_2 <Kg is indicated to provide a semi-quantitative visualization of the CO_2 in the patient airway. It is an adjunct in patient assessment to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician. Intended for use with neonate and infant patients from 250g to 6 kg.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 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

510(k) Number: K083056