K031814

AUG 14 2003

ENCLOSURE L

Premarket Notification (510(k) - Mercury Medical StatCO$_2$meter™ End Tidal CO$_2$ Detector with Integrated Airway Pressure Manometer.

Non-Confidential Summary of Safety and Effectiveness

June 10, 2003

Mercury Enterprises, Inc./Mercury Medical
11300 49th St. N.
Clearwater, FL 33762
Tel: (800) 237-6418
Fax: (727) 572-4501

Official Contact: **Wayne Glover**
QA/RA Engineer

Proprietary or Trade Name: StatCO$_2$meter™

Common/Usual Name: End Tidal CO$_2$ detector with Integrated Airway Pressure Manometer

Classification: Class II, CCK, 21 CFR 868.1400

Classification Name: Analyzer, Gas, Carbon Dioxide, Gaseous Phase

Device: StatCO$_2$meter™

Predicate Devices: StatCO$_2$™ (K021576) and Airway Pressure Manometer (K954486)

Device Description:

The Mercury Medical StatCO$_2$meter™ is a fast, durable colorimetric breath indicator for visualization of exhaled CO$_2$ and also measures Airway and PEEP pressure. The StatCO$_2$meter™ 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. The detector may be used during patient transport or in locations where intubations are performed.

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Intended Use:

Indicated Use: The Mercury Medical StatCO$_2$™ End Tidal CO$_2$ Detector with Integrated Airway Pressure Manometer provides a semi-quantitative visualization of the CO$_2$ in the patient airway while measuring Airway and PEEP pressure. 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.

Technical Characteristics: The device has the same technical characteristics as the combination of the following Mercury Medical predicate devices:

StatCO$_2$™ End Tidal CO$_2$ Detector
Airway Pressure Manometer

Non-Clinical Data: Performance and specifications of the device are consistent with all requirements for this device type specified by ISO 5356-1: 1987 – Anesthetic and Respiratory Equipment-Conical connectors-Part 1: Cones and Sockets. ASTM F1054 – Standard Specification for Conical Fittings of 15mm and 22mm sizes.

Environment of Use: Hospital/Transport

Conclusions: The comparison to the predicate devices demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2003

Mr. Wayne Glover
QA/RA Engineer
Mercury Medical
11300-49th Street North
Clearwater, Florida 33762-4800

Re: K031814
Trade/Device Name: StatCO2meter™
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK, CAP
Dated: June 10, 2003
Received: June 12, 2003

Dear Mr. Glover:

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 (301) 594-46. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infector Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ENCLOSURE B

Indications for Use

510(k) Number: K031814 (To be assigned)

Device Name: **StatCO$_2$meter™**

Intended Use: The Mercury Medical StatCO$_2$meter™ End Tidal CO$_2$ Detector with Integrated Airway Pressure Manometer is intended to provide a semi-quantitative visualization of the CO$_2$ in the patient airway while measuring Airway and PEEP pressure. 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K031814

Prescription Use _X_ **or** **Over-the-counter use** __
(Per CFR 801.109)