MAR 1 - 2005

K050066

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

January 7, 2005

Marquest Medical Products, Inc.
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Englewood, CO 80112
(A division of Vital Signs, Inc.)

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Official Contact: Tom Dielmann, Vice President of RA/QA

Proprietary or Trade Name: *C-CO_2™*

Common/Usual Name: Colorimetric Carbon Dioxide Indicator

Classification Name: 73 CCK – Analyzer, Gas, Carbon Dioxide, Gaseous Phase Subsection 868.1400

Intended Device: Colorimetric CO_2 Indicator

Predicate Device: BreGas AB CO_2 Clip – K023820

Device Description: A non-sterile, single use, colorimetric carbon dioxide indicator with integral luer-lock connector, for placement in a gas sampling ported component, located between a tracheal tube and the breathing circuit, to detect exhaled CO_2.

Pressure in the breathing circuit causes a low flow of breathing gas to pass into and through the indicator and vent to the atmosphere. The colorimetric media in the center window of the device indicates the presence of carbon dioxide in exhaled breath on a breath-by-breath basis.

The colorimetric media in the center window is blue when no carbon dioxide is present, green at intermediate concentrations and yellow when approximately 5% carbon dioxide is present. A breath-by-breath color change reflects ventilation of the patient. A permanent blue or blue-green color indicates absence of exhaled carbon dioxide. A damaged indicator will exhibit a permanent yellow or white color.

The indicator has a color scale against which the actual color may be compared to provide an approximate carbon dioxide concentration. Normal breathing gases, anesthetic gases, or water vapor do not affect the indicator.

510(k) SUMMARY OF SAFETY & EFFECTIVENESS (cont.)

Indicated Use:	The C-CO2 colorimetric carbon dioxide indicator provides a semi-quantitative visualization of the CO2 in the patient airway or in the gas exhaled from a patient. It is an adjunct to clinical assessment when verifying correct ET tube placement and respiration.
Targeted Population:	Patients with a tidal volume greater than or equal to 150ml and with a minute volume greater than or equal to 3L/minute, and with a breathing rate less than or equal to 35 breaths per minute.
Environment of Use:	Hospital, Transport

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Thomas W. Dielmann
Vice President, Regulatory Affairs/Quality Assurance
Marquest Medical Products, Incorporated
11039 East Lansing Circle
Englewood, Colorado 80112

Re: K050066
Trade/Device Name: C-CO_2™ Colorimetric CO_2 Indicator
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: January 7, 2005
Received: January 14, 2005

Dear Mr. Dielmann:

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,

for 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: K_____

DEVICE NAME: C-CO_2™ COLORIMETRIC CO_2 INDICATOR

INDICATIONS FOR USE: The C-CO_2 colorimetric carbon dioxide indicator provides a semi-quantitative visualization of the CO_2 in the patient airway or in the gas exhaled from a patient. At is an adjunct to clinical assessment when verifying correct ET tube placement and respiration.

Prescription Use __X__ and/or Over-The-Counter Use
(per 21 CFR 801 Subpart D)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K050066