DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 1998

Mr. Robert H. Schiffman
Novametrix Medical Systems, Inc.
56 Carpenter Lane
Wallingford, CT 06492

Re: K982499
CO_2SMO Plus! With NICO
Regulatory Class: II (two)
Product Code: 73 BZC
Dated: July 17, 1998
Received: July 20, 1998

Dear Mr. Schiffman:

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 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). 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.

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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982499

Device Name: CO_2SMO Plus! with NICO

Indications For Use:

The intended use of the *CO_2SMO Plus! with NICO* is to provide:

- cardiac output monitoring via the method of partial rebreathing in adult patients receiving mechanical ventilation during general anesthesia and in the intensive care unit (ICU).

- spirometric, carbon dioxide and pulse oximetry monitoring in neonatal, pediatric and adult patients during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED). Separate flow sensors and CO_2 airway adapters are provided for pediatric/adult and neonatal use.

It is intended to be used by trained operators when spirometric, capnographic, pulse oximetry, or cardiac output monitoring is indicated in the judgement of a physician.

It is intended that:

- the neonatal flow and combined CO_2/flow sensors be used with ET tube sizes less than or equal to 4 mm and
- the pediatric/adult flow and combined CO_2/flow sensors be used with ET tube sizes greater than 4 mm or with 22 mm ID breathing circuit devices such as a mouthpiece.

The fittings of the flow sensors and CO_2 airway adapters comply with ISO [5356-1: 1987 (E)].

The flow sensors and CO_2 airway adapters may be used in conjunction with endotracheal tubes, face masks, and breathing circuit devices that also comply with the same fitting specification.

The flow sensors, combination CO_2/flow sensors, single patient use CO_2 airway adapters and valve assembly are single patient use devices.

The *CO_2SMO Plus! with NICO* can calculate additional parameters such as cardiac output, pulmonary capillary blood flow, cardiac index, stroke volume and systemic vascular resistance.

The use of the *CO_2SMO Plus! with NICO* is contraindicated in patients in which a small rise (3-5 mmHg) in their arterial partial pressure of CO_2 level cannot be tolerated.

(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)

10-15-98

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982499

(Optional Format 1-2-96)