JAN 1 2 2000

K992116

510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: June 11, 1999

2. Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens INFINITY etCO2 Pod

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	73CCK	II	868.1400

3. Predicate Device Identification:

Siemens SC9000 etCO2 Module
510(k) K954632

Novametrix CO2SMO Plus
510(k) K963380

4. Device Description:

The INFINITY etCO2 Pod is an addition to Siemens SC8000/SC7000/SC9000XL INFINITY modular bedside monitoring series. When connected to an INFINITY modular bedside monitor the etCO2 pod will measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate.

5. Intended Use:

The intended use of Siemens INFINITY etCO2 pod is to measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in both mainstream and side-stream measurement modes (side-stream is not intended for use in the neonatal population). In conjunction with an INFINITY modular bedside monitor, visual and audible alarms will be produced if any of these parameters vary beyond preset limits, and timed or alarm recordings will be produced.

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Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
USA
Tel: (978) 907-7500
Fax: (978) 750-6879
Telex: 511958 (Siemensm SD)

6. Table of Device Similarities and differences to predicate device

	Predicate Device	Predicate Device	Applicant	Explanation of Differences
Manufacturer	Siemens Medical Systems SC9000 etCO2 Module	Novametrix Medical Systems CO2SMO Plus	Siemens Medical Systems INFINITY etCO2 Pod	
510(k) Number	K954632	K963380	To be assigned	
Intended Use	To measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in both mainstream and side-stream measurement modes (side-stream is not intended for use in the neonatal population). In conjunction with the SC9000, visual and audible alarms will be produced if any of these parameters vary beyond preset limits, and timed or alarm recordings will be produced.	To provide spirometric, carbon dioxide and pulse oximetry monitoring	To measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in both mainstream and side-stream measurement modes (side-stream is not intended for use in the neonatal population). In conjunction with the SC 7000 / SC 8000 / SC 9000XL monitors, visual and audible alarms will be produced if any of these parameters vary beyond preset limits, and timed or alarm recordings will be produced.	Siemens etCO2 pod does not measure or display spirometry or pulse oximetry
Intended Population	Adult/Pediatric	Adult/Pediatric/Neonatal	Adult/Pediatric/Neonatal	
Intended Environment	A healthcare environment by healthcare professionals	Same	Same	
Measuring Capabilities				
Displayed parameters	EtCO2, iCO2, Respiration rate (RRc)	Spirometry, Pulse oximetry, EtCO2, iCO2, Respiration rate (RRc)	EtCO2, iCO2, Respiration rate (RRc)	Siemens etCO2 pod does not measure or display spirometry or pulse oximetry
Display Scales	0-40, 0-80 mmHg	0-50, 0-75, 0-100 mmHg	0-40, 0-60, 0-80, 0-100 mmHg	More display flexibility
Measuring method	Dual-wavelength, non-dispersive infrared	Same	Same	
Measuring capabilities	Mainstream and Sidestream	Same	Same	
Measuring range	0 to 99 mmHg CO2 partial pressure	0 to 100 mmHg partial pressure	0 to 100 mmHg CO2 partial pressure	*A CO2 $\geq$ 100 is considered out of range
Averaging	Breath, 10s, 20s	Breath, 10s, 20s, Instantaneous	Breath, 10s, 20s, Instantaneous	Improvement

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7. Assessment of non-clinical performance data for equivalence: Section T

8. Assessment of clinical performance data for equivalence: Section V

9. Biocompatability:
Not applicable

10. Sterilization:
Not applicable

11. Standards and Guidances: EN 864: 1996
IEC 60601-1

COMPANY CONFIDENTIAL
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USA
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Telex: 511958 (Siemensm SD)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2000

Mr. David Simard
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923

Re: K992116
Siemens INFINITY etCO_2 Pod
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: October 15, 1999
Received: October 15, 1999

Dear Mr. Simard:

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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: **Siemens INFINITY etCO2 Pod**

Indications for Use:

Siemens INFINITY etCO2 is indicated for use in the adult, pediatric and neonatal populations, in an environment where patient care is provided by healthcare professionals, i.e. Physicians, Nurses, Technicians, when the professional determines that the device is required to measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in either mainstream or side-stream measurement mode (side-stream mode is not intended for use in the neonatal patient population). In conjunction with the SC 7000 / SC 8000 / SC 9000XL monitors, visual and audible alarms will be produced if any of these parameters vary beyond preset limits, and timed or alarm recordings will be produced.

MRI Compatibility Statement:
The Siemens INFINITY etCO2 Pod is not intended for use in a MRI magnetic field.

(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)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992116