AUG 12 1998

K980287

510(k) Notification
Siemens SC9000/SC9015 Transcutaneous Gas Module (tpO2/CO2)

510(k) SUMMARY
as required per 807.92(c)

2. Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (508) 750-7500
Fax: (508) 777-3398
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Jacqueline Emery

Date submission was prepared: January 23, 1998

3. Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens Transcutaneous tpO2/CO2 Gas Module

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

Common Name	Classification Number	Class	Regulation Number
Monitor, Carbon-Dioxide, Cutaneous	73LKD	II	868.2480
Monitor, Oxygen, Cutaneous, for infant not under gas anesthesia	73KLK	II	868.2500

4. Predicate Device Identification:

Siemens SIRECUST Transcutaneous ~~Carbon Dioxide Monitoring~~ System
510(k) Number: K891481A (O2 sensor, Radiometer K900333)

5. Device Description:

The Transcutaneous Gas Module (tpO/CO2 pod) is an addition to Siemens SC9000 patient monitoring series which provides transcutaneous measurement of partial pressures of the O2 and CO2 in the peripheral tissue of a patient.

6. Intended Use:

The intended use of Siemens Transcutaneous tpO2/CO2 Gas Module is for the continuous, noninvasive trend monitoring of transcutaneous oxygen and transcutaneous carbon dioxide partial pressure, in the neonatal patient population when the patient is not under gas anesthesia, by healthcare professionals, i.e. Physicians, Nurses, Technicians.

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

(9)

7. Table of Device Similarities and differences to predicate device

	Substantial Equivalent Device Siemens Medical Systemst SIRECUST 404/404N	Substantial Equivalent Device Radiometer America, Inc. Combined Transcutaneous TcPO2/TcPCO2 Elect.	Applicant Siemens Medical Systems SC9000/SC9015 tpO2/CO2 module
Manufacturer	Siemens Medical Systems	Radiometer	Siemens Medical Systems
510(k) Number	K891481	K900333	To be assigned
Intended Use	Continuous, noninvasive trend monitoring of transcutaneous carbon dioxide partial pressure		Same
Intended Population	Adult, Neonatal		Neonatal
Intended Environment	In an environment where healthcare is provided by healthcare professionals, i.e. doctors, nurses, technicians.		Same
O2 only sensor		Solid State	Same
O2 + CO2 sensor	Solid State	Solid State	Same
tpO2 Measuring Range		0 to 800 mmHg	Same
Correction Factor		No	Same
Temperature setting		37 to 45°C	Same
Heating Power		0 to 600 mW ± 10 mW	Same
Calibration		Single point	Same
Alarm		Alarms >.2°C from the selected electrode temperature	User Selectable
tpCO2 Measuring Range	0 to 200 mmHg		Same
Correction Factor	Yes		Same
Temperature setting	37 to 45°C		Same
Heating Power	0 to 600 mW ± 10 mW		Same
Calibration	Single point		Same
Alarm	Alarms >.2°C from the selected electrode temperature		User Selectable
Oxycardiorespirogram	In conjunction with HR + RESP values		Same

8. Assessment of non-clinical performance data for equivalence: Currently there are no FDA standards for this device.

9. Assessment of clinical performance data for equivalence:
The transcutaneous gas module (tpO2/CO2) was deemed to be safe and effective. See Section V of this submission.

10. Biocompatability:
Not applicable

11. Sterilization:
Not applicable

12. Standards and Guidances:
IEC 601-1 Type CF Applied Part

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1998

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

Re: K980287
SC9000/SC9015 Transcutaneous Gas Module (tpO2/tpCO2 pod)
Regulatory Class: II (two)
Product Code: 73 KLK
Dated: May 20, 1998
Received: May 22, 1998

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,

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): K980287

Device Name: **Siemens Transcutaneous TpO2/CO2 Gas Module**

Indications for Use:

Siemens Transcutaneous tpO2/CO2 Gas Module is indicated for use to continuously monitor the noninvasive trending of transcutaneous oxygen in the neonatal population when the patient is not under gas anesthesia.

Siemens Transcutaneous tpO2/CO2 Gas Module is indicated for use to continuously monitor the noninvasive trending of transcutaneous carbon dioxide partial pressure in any patient population.

The device is indicated for use 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.

MRI Compatibility Statement:
The Siemens tpO2/CO2 gas module is not intended for use in an 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 _____