FEB 22 2000

510(k) Notification
INFINITY SC 6002XL Portable Patient Monitor

K993974

510(k) SUMMARY

as required per 807.92(c)

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: November 23, 1999

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens INFINITY SC 6002XL Portable Patient Monitor

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

Common Name	Classification Number	Class	Regulation Number
Cardiac Monitor	74DRT	II	21 CFR 870.2300
Pulse Rate Monitor	74BWS	II	21 CFR 870.2300
Pulse Oximeter	74DQA	II	21 CFR 870.2700
Breathing Frequency Monitor	73BZQ	II	21 CFR 868.2375
Clinical Electronic Thermometer	80BWX	II	21 CFR 880.2910
Indwelling Blood Pressure Monitor	74CAA	II	21 CFR 870.1110
Noninvasive Blood Pressure Monitor	74DXN	II	21 CFR 870.1130
Heart Rate Monitor, Neonatal	74FLO	II	21 CFR 870.2300
Ventilatory Effort Monitor (Apnea Detector)	73FLS	II	21 CFR 868.2375
Monitor Blood Pressure, Neonatal, Invasive	74FLP	II	21 CFR 870.1110
Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	73CCK	II	21 CFR 868.1400
Arrhythmia Detector & Alarm System	74DSI	III	21 CFR 870.1025
Monitor, Physiological, Patient (with arrhythmia detection or alarms)	MHX	III	21 CFR 870.1025

Predicate Device Identification:

K980882	SC 7000 / SC 9000XL INFINITY Modular Bedside Monitor
K982730	SC 7000 / SC 9000XL INFINITY Modular Bedside Monitor
K944350	SC 6000 / SC 6000P
K962404	SC 6000 / SC 6000P Neonatal
K955743	SC 6000 / SC 6000P w/Arrhythmia

Other relevant submissions

K983980	MVWS INFINITY Telemetry System Additional Arrhythmia Calls
K955059	SC3000 MULTIVIEW WorkStation and Remote Display
K992116	INFINITY etCO2 Pod

Device Description:
The INFINITY SC 6002XL is an addition to Siemens INFINITY patient monitoring series that has combined the technologies of two predicate devices: the INFINITY SC 600X and the INFINITY SC 7000. Like the SC 600X the INFINITY SC 6002XL is a compact, configured monitor whose small size allows for ease of portability. Modifications have been made to the SC 600X software to make it more analogous to the SC 7000 platform. The front panel display is similar in design to the SC 7000 for a more uniform look to the INFINITY product line. In addition to A/B clinical performance tests that compared the new INFINITY SC 6002XL to the SC 7000, in-house verification and validation tests were performed. All tests confirmed that the new INFINITY SC 6002XL is as safe and effective as the predicate devices.

Intended Use:
The intended use of the SC 6002XL is substantially equivalent to that of the predicate devices in that it monitors heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation and pulse rate, central apnea, and end-tidal carbon dioxide. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to Siemens R50 recorders, either directly or via the INFINITY network.

Assessment of non-clinical performance data for equivalence:
Substantially equivalent (Section U)

Assessment of clinical performance data for equivalence:
Substantially equivalent (Section V)

Biocompatability:
Not applicable

Sterilization:
Not applicable

Standards and Guidance: Section S

COMPANY CONFIDENTIAL
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879

Table of Device Similarities and differences to legally marketed device

Manufacturer	Legally Marketed Device SC 600X Siemens Medical Systems	Legally Marketed Device SC 7000 Same	Modified Device INFINITY SC 6002XL Same	Explanation of Differences
Intended Use	The intended use of this device is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia (adult), temperature, arterial oxygen saturation, pulse rate, and (central) apnea. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to the Siemens SIRENET or Infinity (Olympus) network	The intended use of this device is to monitor heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation and pulse rate, cardiac output, central apnea, end-tidal carbon dioxide, ST segment analysis, 12-Lead ST segment analysis, and transcutaneous oxygen & transcutaneous carbon dioxide. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to Siemens R50 recorder, either directly or via the INFINITY network.	The intended use of this device is to monitor heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation and pulse rate, central apnea, end-tidal carbon dioxide. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to Siemens R50 recorders, either directly or via the INFINITY network.	ST segment analysis, 12-lead ST segment analysis, transctaneous oxygen & transcutaneous carbon dioxide, and cardiac output are not available.
Intended Population	Adult/Pediatric/Neonatal	Same	Same	
Intended Environment	In a healthcare environment where patient care is provided by healthcare professionals.	Same	Same	
Display type	Color TFT, 6" diagonal	Color TFT, 10.4" diagonal	Color TFT, 6.7" diagonal	New mechanical design
Weight	2.9 kg (6.63 lb) with battery	7.2 kg (15.9 lbs) with battery	3.42 kg (7.54 lb) with lead-acid battery 3.22 kg (7.10 lb) with lithium-ion battery	New mechanical design
Dimensions (H x W x D)	189 x 225 x 131 mm (7.4 x 8.9 x 5.2 in.)	224 x 330 x 190 mm (8.8 x 13.0 x 7.5 inches)	196 x 223 x 134 mm (7.7 x 9.8 x 5.3 inches)	New mechanical design

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2000

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

Re: K993974
INFINITY SC 6002XL Portable Patient Monitor
Regulatory Class: III (three)
Product Code: 74 MHX, MSX
Dated: November 23, 1999
Received: November 24, 1999

Dear Mr. Simard:

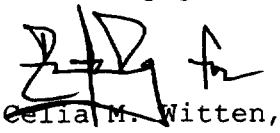
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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): K993974

Device Name: Siemens INFINITY SC 6002XL Portable Patient Monitor

Indications for Use:
This device is capable of monitoring:

- Heart Rate
- Respiration Rate
- Invasive Pressure
- Non-Invasive Pressure
- Arrhythmia
- Temperature
- Arterial oxygen saturation
- Pulse rate
- (central) apnea
- end-tidal CO2

The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The devices are intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of Arrhythmia which is not intended for the neonatal population.*

MRI Compatibility Statement:
The Siemens INFINITY SC 6002XL is not compatible 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)

2/22/00

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number_____