FEB 1 5 2002

K020144
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1. 510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Regulatory Submissions Manager
Date submission was prepared: January 14, 2002

2. Trade Name, Common Name and Classification Name:

A. Trade Name:
Siemens INFINITY SC 6002XL Modifications

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

Common Name	Product Code	Class	Regulation Number
Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)	MHX	III	870.1025
Arrhythmia Detector & Alarm	74DSI	III	870.1025
System, Network and Communication, Physiological Monitors	MSX		

3. Legally Marketed Device:
Siemens INFINITY SC 6002XL
K993974, K002105

4. Device Description:

SC 6002XL Wireless Option
A wireless ethernet adapter installed in the PCMCIA port communicates with the INFINITY Network (K955059) through installed access points hardwired to the network. All patient related and network data is transmitted to the pre-installed access points allowing the transmitted data from the monitor to be viewed at an assigned MultiView WorkStation (K955059). This configuration provides the network with the same functionality as a hardwired system.

The MultiView WorkStation supports wireless operation by providing information to the SC6002XL allowing the monitor to have a unique network address. Once the SC6002XL has established itself on the network, the MultiView WorkStation has no new functionality. MultiView WorkStation hazards identified with the MVWS support of the wireless functionality have been addressed in MVWS VF2 software.

SC 6002XL with Full Arrhythmia Option

The SC 6002XL VF1 release includes the Full Arrhythmia Option. With this option eight additional arrhythmia calls are enabled. The arrhythmia algorithm is the same algorithm found in Siemens MVWS INFINITY Telemetry (K003179), as well as Siemens patient monitors, including: SC 7000 / SC 9000XL (K980882) and SC 8000 (K983632). Previous releases of the SC 6002XL (K993974 and K002105) included the same arrhythmia algorithm, however, in the first two releases of the SC 6002XL only the Basic Arrhythmia functionality, with fewer arrhythmia calls was made available.

Fourth Channel Option

In addition, to provide customers with more readily available information, a fourth channel is being made available. The fourth channel is also a locked option.

5. Intended Use:

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, and ST Segment Analysis. 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.

6. Assessment of non-clinical performance data for equivalence: Section L

7. Assessment of clinical performance data for equivalence: Not applicable

8. Biocompatability: Not applicable

9. Sterilization: Not applicable

10. Standards and Guidances: IEEE 802.11
Standard for Wireless Medium Access Method (MAC) and Physical Layer (PHY)

COMPANY CONFIDENTIAL

Siemens Medical Solutions, USA
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 1 5 2002

Ms. Penelope H. Greco
Manager, Regulatory Submissions
Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K020144
Trade Name: Siemens Medical INFINITY SC 6002XL (VF1)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector & Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: January 14, 2002
Received: January 16, 2002

Dear Ms. Greco:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020144

Device Name: Siemens INFINITY SC 6002XL Modifications

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
- ST Segment Analysis

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.

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 in the Adult, Pediatric and Neonatal populations, *with the exception of Arrhythmia and ST Segment Analysis which are 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)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020144