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510(k) SUMMARY

as required per 807.92(c)

JUL 20 2001

Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
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Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: June 26, 2001

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens Medical Information Bus (MIB II) Protocol Converter

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	21 CFR 870.1025
Arrhythmia detector & Alarm	74DSI	III	21 CFR 870.1025

Legally Marketed Device Identification:

Siemens SC 8000 K983632
SC 8000 w/Advanced Communication Option, K990563
Siemens INFINITY MIB II Protocol Converter, K010640

Description of Modification:

The SC 8000 Advanced Communication Option II is equivalent to that submitted in K990563 in that it converts signals, to a form that the SC 8000 can process and display, from external devices:

MultiGas and MultiGas+ modules (K965062)
Surgical Display Controller (K970348)
Medical Information BUS Protocol Converter (MIB and MIB II)
(K970368, K973222, K99166, K003248, and K010640)

A modification has been implemented in the SC 8000 Advanced Communication Option II to accommodate RJ45 connectors for interfacing to the MIB II Protocol Converter (K010640). The MIB II Protocol Converter supports the new IEEE 1073.3.2-2000, Standard for Medical Communications – Transport Profile – irDA Based – Cable Connected.

Intended Use:

The INFINITY SC 8000 monitor is intended for multi-parameter patient monitoring. The device will produce visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced. This device will connect to a Siemens R50 Bedside recorder, either directly or via the INFINITY Network.

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Special 510(k): Device Modification
SIEMENS INFINITY SC 8000 with Advanced Communication Option II

Assessment of non-clinical performance data for equivalence: Section J

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances:
1073.3.2 – 2000 IEEE Standard for Medical Communications
Transport Profile – IrDA Based – Cable Connected

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2001

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

Re: K012016
Trade Name: INFINITY SC 8000 with Advanced Communications Option II
Regulation Number: 21 CFR 870.1025
Regulatory Class: III (three)
Product Code: 74 MHX
Dated: June 26, 2001
Received: June 28, 2001

Dear Ms. Greco:

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 control provisions of the Act. The general control 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) 594-4645. 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 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,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indicated Use Statement

510(k) Number (if known): K012016

Device Name: INFINITY SC 8000 Monitor

Indications for Use:

The INFINITY SC 8000 Monitor is capable of monitoring:

- Heart rate
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Arrhythmia
- Temperature
- Cardiac output
- Arterial oxygen saturation
- Pulse rate
- Apnea
- ST Segment Analysis
- 12-Lead ST Segment Analysis
- tcpO2/tcpCO2
- EEG signals
- FiO2

With the MultiGas and MultiGas+ modules the monitor is capable of measuring respiration rate, Inspired and expired Carbon Dioxide (CO2), inspired and expired Oxygen (MultiGas+ only), average inspired Oxygen (MultiGas only), inspired and expired gas concentrations of Enflurane, Halothane, Isoflurane, Desflurane, Sevoflurane, and Nitrous Oxide.

With etCO2 the monitor can measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in either mainstream or side-stream measurement mode

With the INFINITY etCO2 + Respiratory Mechanics Pod the monitor can provide spirometric and carbon dioxide monitoring.

The monitor can interface with specific third party devices via an MIB protocol converter.

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

The device is intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output and ST Segment Analysis which are intended for use in the adult and pediatric populations only; Arrhythmia which is not intended for use in neonatal mode; and tcpO2 which is to be used in the neonatal population only when the patient is not under gas anesthesia.*

MRI Compatibility Statement:
The INFINITY SC 8000 Monitor 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 K012016