MAY

Special 510(k): Device Modification
SIEMENS Medical Information Bus (MIB) Protocol Converter

K991661

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
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Official Correspondent: David Simard, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: May 5, 1999

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens Medical Information Bus (MIB) Protocol Converter

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

Common Name	Classification Number	Class	Regulation Number
Transducer Signal amplifier and conditioner	73 DQA	II	21 CFR 870.2060

Legally Marketed Device Identification:

Siemens Medical Information Bus (MIB) Protocol Converter: 510(k) K970368 and K973222.

Description of Modification:

The Medical Information Bus (MIB) Protocol Converter has received two 510(k) clearances.

1. 510(k) K970368 was cleared for interface with Siemens SV300 ventilator and the Baxter Vigilance blood gas/continuous cardiac output monitor.
2. 510(k) K973222 was cleared for interface with Puritan Bennett 7200 ventilator, the Draeger Evita II, Draeger Evita IV, and Draeger Babylog ventilators, and Siemens SV900 ventilator.

Minor software modifications have been made to Siemens Medical Information Bus (MIB) Protocol Converter and device specific accessory cables are now available that allow interface connections for the following devices to the INFINITY modular bedside monitors (SC9000/SC7000/SC9000XL/SC8000). The monitor may alarm for some MIB anesthesia parameters independent of the anesthesia machine's alarms.

Anesthesia Systems
- Dräger Narkomed II
- Dräger Narkomed IV
- Dräger Julian
- Ohmeda 7900 / Modulus CD Anesthesia Machine

Oximeter
- Abbott Oximetrix 3

Point of Care Blood Gas Analyzers

AVL Medical Instruments
- Opti Critical Care Analyzer, Portable Blood Gas Analyzer

Optical Sensors Inc.
- OSI – Optical CAM

VIA Medical
- VIA V-ABG1 Blood Gas Chemistry Monitor

Intended Use:

Siemens Medical Information Bus (MIB) Protocol Converter is intended to connect third party medical devices that do not provide data per the IEEE1073 Medical Information Protocol Standard to the Siemens INFINITY Modular Bedside Monitors for display, such as:

Siemens SV 300 ventilator
Baxter Vigilance blood gas/continuous cardiac output monitor
Siemens SV900 ventilator
Draeger Evita II ventilator
Draeger Evita IV ventilator
Draeger Babylog ventilator
Puritan Bennett 7200 ventilator
Draeger Narkomed II Anesthesia System
Draeger Narkomed IV Anesthesia System
Draeger Julian Anesthesia Machine
Ohmeda 7900 / Modulus CD Anesthesia Machine
Abbott Oximetrix 3 Oximeter
AVL Medical Instruments: Opti Critical Care Analyzer, Portable Blood Gas Analyzer
Optical Sensors Inc.: OSI – Optical CAM
VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor

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

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: 1073.3.1 – 1994 IEEE Standard for Medical Device Communications Transport Profile – Connector Mode
1073.4.1 – 1994 IEEE Standard for Medical Device Communications Physical Layer Interface – Cable Connected

COMPANY CONFIDENTIAL

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1999

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

Re: K991661
Siemens Medical Information Bus (MIB) Protocol Converter
Regulatory Class: II (two)
Product Code: 73 DQA
Dated: May 5, 1999
Received: May 14, 1999

Dear Mr. Simard:

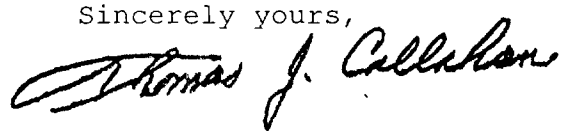
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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



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):_____

Device Name: Siemens Medical Information Bus (MIB) Protocol Converter

Indications for Use:

The Medical Information Bus (MIB) Protocol Converter is indicated for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that third party medical devices that do not provide data per the IEEE 1073 Medical Information Protocol Standard should be connected to the Siemens INFINITY Modular Bedside Monitors for display, such as:

Siemens SV 300 ventilator
Baxter Vigilance blood gas/continuous cardiac output monitor
Siemens SV900 ventilator
Draeger Evita II ventilator
Draeger Evita IV ventilator
Draeger Babylog ventilator
Puritan Bennett 7200 ventilator
Draeger Narkomed II Anesthesia System
Draeger Narkomed IV Anesthesia System
Draeger Julian Anesthesia Machine
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Abbott Oximetrix 3 Oximeter
AVL Medical Instruments: Opti Critical Care Analyzer, Portable Blood Gas Analyzer
Optical Sensors Inc.: OSI – Optical CAM
VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor

Arthur A. Carlucci

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991661

MRI Compatibility Statement:
The Medical Information Bus (MIB) Protocol Converter 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)