510(k) AMENDMENT SUMMARY

as required per 807.92(c)

2. Submitters Name, Address:

SEP - 4 1997

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (508) 750-7500
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Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Jacqueline E. M. Emery
Date amendment to 510(k) K970368 was prepared: August 8, 1997

3. Trade Name, Common Name and Classification Name:

A. Trade Name: (Same as original submission)

Siemens SC9000/ SC9015 Series Medical Information Bus (MIB) Protocol Converter [510(k) K970368 cleared May 6, 1997]

B. Common Name, Classification Name, Class and Regulation Number: (Same as original submission)

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

4. Predicate Device Identification: (Same as original submission)

Hewlett-Packard Model M1032A Vuelink Interface Plug In Module cleared under 510(K) number: K923682

5. Device Description: (Same as original submission)

The Siemens SC9000/SC9015 Series Medical Information Bus (MIB) Protocol Converter transforms data generated by third party devices (e.g. ventilators, SvO2 devices and infusion pumps) into a common format per the IEEE 1073 Medical Information Protocol and transmits this data to the Siemens SC9000/SC9015 Bedside Monitor. Attachment cables specific to third party devices are offered as accessories.

6. Intended Use:

The Medical Information Bus (MIB) Protocol Converter is intended to connect third party medical devices such as Siemens SV300™ ventilator, Baxter Vigilance™ blood gas/continuous cardiac output monitor, Siemens SV900™ ventilator, Puritan Bennett 7200™ ventilator, and the Draeger Evita II™, Draeger Evita IV™ and Draeger Babylog™ ventilators that do not provide data per the IEEE 1073 Medical Information Protocol Standard to the Siemens SC9000/SC9015 Bedside Monitor for display.

7. Table of Device Similarities and differences to predicate device
(Same as original submission)

	Substantial Equivalent Device Hewlett Packard Co Model MI032A VueLink Module	Applicant Siemens Medical Systems SC9000/9015 Series Medical Information Bus (MIB) Protocol Converter (Amendment)
Manufacturer	Hewlett Packard	Siemens Medical Systems – Electromedical Systems Group, PCS
510(k) Number	K923682	~~K970368~~ K973222
Intended Use	Provides an external device interface capability to third party devices that have a serial RS-232 and/or analog output	Same
Intended Population	NA Not connected to patients	Same
Intended Environment	OR or ICU	Same
Input port	RS-232, Analog, Analog/Digital combination	Same
Output port	HP specific	IEEE 1073 (MIB connector)

8. Assessment of non-clinical performance data for equivalence: (Same as original submission)
Substantial equivalence is claimed to the Hewlett Packard Model M1032A VueLink Interface Plug-In Module cleared under 510(k) number K923682.

9. Assessment of clinical performance data for equivalence: Not applicable
(Same as original submission)

10. Biocompatability: Not applicable (Same as original submission)

11. Sterilization: Not applicable (Same as original submission)

12. Standards and Guidances: (Same as original submission)
Currently, there are no FDA standards for this device. However, the Siemens SC9000/SC9015 Series Medical Information Bus (MIB) Protocol Converter complies with:

- 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 Conn

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP - 4 1997

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

Re: K973222
Siemens SC9000/SC9015 Series Medical Information Bus (MIB) Protocol Converter for the Puritan Bennett 7200™, the Draeger Evita II™, IV™, Babylog™, and Siemens SV900™ Ventilators
Regulatory Class: II (two)
Product Code: 73 DQA
Dated: August 18, 1997
Received: August 21, 1997

Dear Mr. Cohen:

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 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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): K973222

Device Name: Siemens SC9000/SC9015 Series Medical Information Bus (MIB) Protocol Converter

Indications for Use:

The Siemens SC9000/SC9015 Series 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 the Siemens SV300™ ventilator, Baxter Vigilance™ blood gas/continuous cardiac output monitor, Siemens SV900™ ventilator, Draeger Evita II™, Evita IV™, and Draeger Babylog™ ventilators, and Puritan Bennett 7200™ ventilator should be connected to the Siemens SC9000/SC9015 Bedside Monitor for display.

MRI Compatibility Statement:
The Siemens SC9000/SC9015 Series Medical Information Bus (MIB) Protocol Converter is not compatible 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)

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

510(k) Number K973222