

K970368

510(k) SUMMARY
as required per 807.92(c)

MAY - 6 1997

2: Submitters Name, Address:

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Date submission was prepared: January 7, 1997

3: Trade Name, Common Name and Classification Name:

A. Trade Name: Siemens SC9000/ SC9015 Series Medical Information Bus (MIB) Protocol Converter

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

Common Name	Classification Number	Class	Regulation Number
Transducer Signal amplifier and conditioner	73 DQA	II	21CFR870.2060

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

5. Device Description: 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 device are offered as accessories.

6. Intended Use: The Medical Information Bus (MIB) Protocol Converter is intended to connect third party medical devices that do not provide data per the IEEE 1073 Medical Information Protocol Standard to the Siemens SC9000/SC9015 Bedside Monitor for display.

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510 (K) Notification

Siemens SC9000/SC9015 Medical Information Bus (MIB) Protocol Converter

7. Table of device similarities and differences to predicate device

	Substantial Equivalent Device Hewlett Packard Co Model M1032A VueLink Module	Applicant Siemens Medical Systems SC 9000/9015 Series Medical Information Bus (MIB) Protocol Converter
Manufacturer	Hewlett Packard	Siemens Medical Systems - Electromedical Group
510K Number	K923682	To be assigned
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. Assesment of non-clinical performance data for equivalence:

Substantial equivalence is claimed to the Hewlett Packard Model M1032A Vuelink Interface Plug-In Module cleared under 510(K) number K923682.

9. Assesment of clinical performance data for equivalence: Not applicable

10. Biocompatibility: Not applicable

11. Sterilization: Not applicable

12. Standards and Guidances:

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 Connected

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