JAN 29 1997

K962291

510(k) SUMMARY

as required per 807.92(c)

2: Submitters Name, Address:

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Date submission was prepared: June 1, 1996

3: Trade Name, Common Name and Classification Name:

A. Trade Name: Siemens SC9000/ SC9015 Bedside Monitoring System

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

Common Name	Classification Number	Class	Regulation Number
Cardiac monitor	74DRT	II	21 CFR 870.2300
Arrhythmia detector & Alarm System	74DSI	III	21 CFR 870.1025
Breathing frequency monitor	73BZQ	II	21 CFR 868.2375
Pulse rate monitor	74BWS	II	21 CFR 870.2300
Non-indwelling blood pressure monitor	74DXN	II	21 CFR 870.1130
Clinical electronic thermometer	80BWX	II	21 CFR 880.2910
Pulse Oximeter	74DQA	II	21 CFR 870.2700
Cardiac Output Monitor	74KFN	II	21 CFR 870.1435
end-tidal Carbon-Dioxide Monitor	73CCK	II	21 CFR 868.1400
Indwelling Blood Pressure Monitor	74CAA	II	21 CFR 870.1110
Indwelling blood pressure monitor	74CAA	II	21 CFR 870.1110
Heart Rate Monitor, Neonatal	74FLO	II	21 CFR 870.2300
Ventilatory Effort Monitor (Apnea Detector)	73FLS	II	21 CFR 868.2375
Monitor Bloodpressure, Neonatal, Invasive	74FLP	II	21 CFR 870.1110

4: Predicate Device Identification:
The Siemens Sirecust 1260/1261/1280/1281/960/961 series Neonatal Monitoring system, 510(K) file number K952054.

5. Device Description
The Siemens SC9000/ SC9015 Bedside Monitoring System. with enhanced Neonatal Functionality is an enhanced software version of the Siemens SC9000/ SC9015 Bedside Monitoring System. The enhancement adds neonatal monitoring.

6. Intended Use:
The intended use of this device is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, cardiac output, arterial oxygen saturation, pulse rate, cardiac output, end-tidal carbon dioxide and (central) apnea. This device will produce visual and aural alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to the Siemens SIRENET or Infinity (Olympus) network.

7. Table of device similarities and differences to predicate device

	Modified Software **SC9000/ SC9015 Neonatal Monitor**	*Substantially Equivalent Device* **1200 series Neonatal Monitoring System** (K952054)	*Explanation of the modified version differences when compared to the 1200 series Neonatal Monitoring System*
Manufacturer	Siemens Medical Systems EMG	Siemens Medical Systems EMG	
510K number	To be assigned	K952054	
Intended population	Neonatal	Neonatal	Same neonatal application areas
Monitoring parameters	Software modules added for neonatal application: ECG, Respiration (impedance), Cardiac Output, Invassive pressure, Pulse, Temperature, SpO2, non-invasive pressure, etCO2	Software modules for neonatal application: ECG, Respiration (impedance), Cardiac Output, Invassive pressure, Pulse, Temperature, SpO2, non-invasive pressure, etCO2	
Apnea delay time (default)	15 seconds	10 seconds	Apnea alarm time is user selectable. Default was changed to 15 seconds based upon customer preference.
Neonatal Resp. Rate Monitoring (default)	ON	ON	

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	Modified Software **SC9000/ SC9015 Neonatal Monitor**	*Substantially Equivalent Device* **1200 series Neonatal Monitoring System (K952054)**	*Explanation of the modified version differences when compared to the 1200 series Neonatal Monitoring System*
Heart Rate Limits (default)	80 & 170	100 & 170	Default was changed to 80 based upon customer preference.
Resp Rate limits (default) (Impedance)	20 & 60	6 & 85	Defaults were changed based upon customer preference.
Impedance. Resp. Rate Apnea Alarm Grade (Default)	Serious	Serious	
SpO2 Pulse Limit (default)	95 %	100%	Defaults were changed based upon customer preference
Temperature Alarm Limit (default)	34.0 & 39.0 °C	30.0 & 40.0 °C	Defaults were changed based upon customer preference.
etCO2 alarm limits (default)	30 & 50 mmHg	20 &25 mmHg	Defaults were changed based upon customer preference.
Max. NBP cuff inflation time	90 sec.	120 sec.	Reduced per customer preference.
Max. NBP cuff pressure	150 mmHg	150 mmHg	
QRS duration measurement (neonatal)	40 to 120 msec	40 to 120 msec	

8. Assesment of non-clinical performance data for equivalence: Not applicable

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

10. Not applicable

11. Not applicable

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