

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING A DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The 960/961 1260/1261 and 1280/1281 Series Neonatal Monitoring is an enhanced software version of the 960/961 1260/1261 and 1280/1281 Series monitors. The enhanced software version increases the patient population to include neonatal applications. The enhanced software is substantially equivalent to the software used in the Siemens Neonatal Monitor Model 404N (reference 510(K) 844187/A). The Intended Use Statement for the enhanced software is the same as the Intended Use for the Model 404 Neonatal Monitor.

The intended use of this software is to measure: heart rate, respiration rate, invasive blood pressure, noninvasive blood pressure, cardiac output, gaseous carbon dioxide level, temperature, arterial oxygen concentration and pulse rate in neonatal patients and to detect ventilator performance and electroencephalograph waveforms. The software will produce visual and aural alarms if any of these parameters vary beyond preset limits.

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GENERAL INFORMATION

A. TRADE NAME

Siemens Sirecust 1200 Series Neonatal Monitoring which includes:

1260 Neonatal Monitoring (Monochrome Display)

1261 Neonatal Monitoring (Color Display)

1280 Neonatal Monitoring (Monochrome Display)

1281 Neonatal Monitoring (Color Display)

Siemens Sirecust 960 Series Monitoring (Retrofit) which includes:

960 Monitor (Monochrome Display)

961 Monitor (Color Display)

Siemens Sirecust 1200 Series Monitoring (Retrofit)

1260 Monitor (Monochrome Display)

1261 Monitor (Color Display)

1280 Monitor (Monochrome Display)

1281 Monitor (Color Display)

B. COMMON NAME, CLASSIFICATION NUMBER, CLASS, and REGULATION NUMBER

Monitor, Cardiac (Include. Cardiometer & Rate Alarm)	74DRT	II	870.2300
Monitor, Cardiac Output (Thermal)	74KFN	II	870.1435
Monitor, Breathing Frequency	73BZQ	II	868.2365
Monitor, Indwelling Blood Pressure	74CAA	II	870.1110
Monitor, Electrocardiograph	74BRS	II	870.2370
Monitor, Electroencephalograph	84BRR	II	882.1400
Monitor, Temperature	80BWX	II	880.2910
Monitoring Spirometer	73BZK	II	868.1850
Oximeter	74DQA	II	870.2700
Monitor, Carbon Dioxide	73ILKD	II	868.4280
Monitor, Noninvasive Blood Pressure	74BXD	II	876.1130

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C. ESTABLISHMENT REGISTRATION NUMBER

1220063

D. ADDRESS OF MANUFACTURER

Siemens Medical Electronics, Inc.
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Contact Person: Mr. Thomas Connelly

E. NEW OR MODIFICATION

The 960/1260/1280 Series Neonatal Monitoring is an enhanced software version of the 960/1260/1280 Series monitors. The enhanced version increases the patient population to include neonates along with the pediatric and adult patient covered by earlier versions of these products. The Intended Use Statement for the enhanced software is the same as the Intended Use for the Siemens Medical Systems' Model 404N Neonatal Monitor.

The enhanced software (version VH4-HXE) is fully compatible with previously sold versions of these monitors. A retrofit will be offered to the owners of units with the previous revision software (version VGx-HXE and VHx-HXE) where x is the revision number.

INTENDED USE STATEMENT

The 960/1260/1280 Series Neonatal Monitoring is an enhanced software version of the 960/1260/1280 Series monitors. The enhanced version increases the patient population to include neonates along with the pediatric and adult patient covered by earlier versions of these products. The Intended Use Statement for the enhanced software is the same as the Intended Use for the substantially equivalent software of the Model 404N (reference 510(K) 844187/A).

The intended use of this software is to measure: heart rate, respiration rate, invasive blood pressure, noninvasive blood pressure, cardiac output, gaseous carbon dioxide level, temperature, arterial oxygen concentration and pulse rate in neonatal patients and to detect ventilator performance and electroencephalograph waveforms. The software will produce visual and aural alarms if any of these parameters vary beyond preset limits.

Intended Operator:

The Siemens 960/1260/1280 Series Neonatal Monitoring is intended to be used by Healthcare providers, i.e. Physicians, Nurses, and Technicians.

The device labeling contains instructions for use which assures safe and effective use of the device.

CAUTION: Federal law in the United States restricts this device to sale by, or on the order of a physician. All Siemens bedside monitors, parameter cartridges, central displays, recorders, ancillary displays, peripheral equipment, and accessories are intended for use only by qualified medical personnel. Patient monitoring equipment, however sophisticated, should never be used as a substitute for the human care, attention, and critical judgment that only trained health care professionals can provide.

Intended Patient Populations:

The enhanced software for the Siemens 960/1260/1280 Series Neonatal Monitoring is intended to be used with Neonatal populations.

Intended Use Environment:

The Siemens 960/1260/1280 Series Neonatal Monitoring is intended to be used in the environment where patient care is provided by Healthcare Professionals.

Performance Standard: None established under Section 514 or Section 358

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510 (K) Decision Making Chart

- 1. Is the device compared to Marketed device?** Yes, Model 404N Neonatal Monitor (K 844187/A)
Manufactured by Siemens Medical Systems, Danvers, Ma.

- 2. Does the device have the same Indication Statement?** Yes the enhanced software has the same intended use as the predicate device.

- 3. Does the new device have the same intended use and may be “substantially equivalent”?**
Yes the new device uses the same software that is used in the predicate device.

- 4. Does the device have the same Technological Characteristics, e.g. Design, materials, etc?**
Yes, the software is the same as the software used in the predicate device.

- 5. Are the descriptive characteristics precise enough to ensure equivalence?**
Yes, the specifications are identical.

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II. SAFETY AND EFFECTIVENESS INFORMATION

ELECTRICAL:

The results of the environmental, electrical safety, and mechanical test results which were performed on the monitors are presented in Exhibit P.

OPERATION:

The device labeling contains instructions for use which assures safe and effective use of the device.

CAUTION: Federal law in the United States restricts this device to sale by, or on the order of a physician. All Siemens bedside monitors, parameter cartridges, central displays, recorders, ancillary displays, peripheral equipment, and accessories are intended for use only by qualified medical personnel. Patient monitoring equipment, however sophisticated, should never be used as a substitute for the human care, attention, and critical judgment that only trained health care professionals can provide.

DEVELOPMENT:

Medical device development is conducted in accordance with an approved Siemens Product Planning Process. Product specifications, hazards analysis, software development plan and device test plan are required parts of the device development process. Qualification test results which demonstrate that the device performs in accordance with its specification are required before product release.

III. SUBSTANTIAL EQUIVALENCE

The Neonatal Monitors use the same hardware with enhanced software to accommodate the neonatal population of patients. The performance specifications for the neonatal applications are identical to the performance specifications of the Siemens Medical Systems Neonatal Monitor Model 404N (reference 510(K) K844187/A)

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