

K962404

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510(k) SC 6000 & SC 6000 P Neonatal Monitoring Enhancement

Section 2: Summary & Certification

510(k) Summary per 807.92(c)

(2) Subscribers Name & Address:

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(3) Trade Name:

Siemens SC 6000 & SC 6000 P Portable Bedside Monitoring System

Common name, Classification number, Class & Regulation Number:

| Common Name | Classification Number | Class | Regulation Number |
|--|-----------------------|-------|-------------------|
| Cardiac monitor | 74DRT | II | 21 CFR 870.2300 |
| Pulse rate monitor | 74BWS | II | 21 CFR 870.2300 |
| Pulse oximeter | 74DQA | II | 21 CFR 870.2700 |
| Breathing frequency monitor | 73BZQ | II | 21 CFR 868.2375 |
| Clinical electronic thermometer | 80BWX | II | 21 CFR 880.2910 |
| Indwelling blood pressure monitor | 74CAA | II | 21 CFR 870.1110 |
| Noninvasive blood pressure monitor | 74DXN | II | 21 CFR 870.1130 |
| Heart Rate Monitor, Neonatal | 74FLO | II | 21 CFR 870.2300 |
| Monitor Blood pressure, Neonatal, Invasive | 74FLP | II | 21 CFR 870.1110 |
| Arrhythmia detector & Alarm | 74DSI | III | 21 CFR 870.1025 |

(4) Predicate Device Identification:

Siemens SIRECUST 1261 granted premarket approval under 510 K file number K952054.

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(5) Device Description:

The SC 6000 and SC 6000P Portable patient monitors with neonatal monitoring enhancement are software enhanced versions of the SC 6000 and SC 6000P Portable patient monitors. The software modifications have been undertaken to expand the Intended Patient Population from pediatric and adults to also include neonatal patients.

(6) Intended Use of the Device:

The intended use statement for the device is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia(only for adults), temperature, SpO2 and ~~central apnea~~. The device will produce visual and aural alarms if any of the above parameters vary beyond preset limits and produce timed or alarm recordings.

(7) Summary of technological characteristics of Device and Predicate Device:

The comparison of intended use and technological features of these devices to other legally marketed devices taken together with the validation results and other information in this submission indicate that these devices are substantially equivalent to legally marketed predicated devices in safety, effectiveness and intended use.

| Parameter | SC6000 & SC6000 P Specification | Predicate Device: SIRECUST 1261 Specification (When equipped with Large Integrated Module(LIM)) |
|----------------------------------|---|---|
| ECG & Heart Rate | | |
| Available leads: | I, II, III, aVR, aVF, aVL, V | I, II, III, aVR, aVF, aVL, V |
| Measuring range: | 15 - 300 bpm | 15 - 300 bpm |
| Accuracy: | ± 5% for 15 - 200 bpm ± 8% for 201 - 300 bpm | ± 10% for 15 - 300 bpm |
| Respiration | | |
| Method: | Impedance pneumography | Impedance pneumography |
| Measuring range: | 2 - 155 breaths per min. | 2 - 155 breaths per min. |
| Measuring accuracy: | ± 3 bpm | ± 3 bpm |
| Apnea Detection?: | Yes | Yes |
| SpO2 | | |
| Measuring method: | Absorption-spectrophotometry | Absorption-spectrophotometry |
| Measuring range: | | |
| SpO ₂ : | 1 - 100% | 1 - 100% |
| Pulse Rate: | 30 - 300 bpm | 30 - 300 bpm |
| SpO₂ Accuracy: | | |
| Range 70 - 100% | ± 2% | ± 2% |
| Range 0 - 69%: | not specified | not specified |
| Pulse Rate Accuracy: | ± 10% | ± 10% |
| Temperature | | |

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| Parameter | SC6000 & SC6000 P Specification | Predicate Device: SIRECUST 1261 Specification (When equipped with Large Integrated Module(LIM)) |
|--|--|--|
| Measurement Range: | 0° C to 50° C | -5° C to 50° C |
| Accuracy: | | |
| Range 30 - 50°C | ± 0.1°C | ± 0.1°C |
| Range 0 - 30°C | ± 0.2°C | ± 0.2°C |
| Non Invasive Blood Pressure (NBP) | | |
| Parameter display: | Systolic, Diastolic, Mean | Systolic, Diastolic, Mean |
| Measuring method: | Oscillometric technique | Oscillometric technique |
| Measurement range: | | |
| heart rate: | 40-240 bpm | 40-240 bpm |
| systolic pressure | 30-130 mmHg | 30-130 mmHg |
| mean pressure | 20-110 mmHg | 20-110 mmHg |
| diastolic pressure | 10-100 mmHg | 10-100 mmHg |
| Initial inflation pressure: | 110 mmHg +/- 15 mmHg | 110 mmHg +/- 15 mmHg |
| Static cuff accuracy: | ± 3 mmHg | ± 3 mmHg |
| Invasive Blood Pressure (IBP) | | |
| Measuring method: | resistive strain gauge transducer | resistive strain gauge transducer |
| Measuring range: | -50 to + 399 mmHg | -50 to + 399 mmHg |
| Accuracy: After transducer zeroing | ± 2 mmHg exclusive of transducer | ± 2 mmHg exclusive of transducer |
| Transducer specifications | Siemens-approved transducers with a resistance of 200 to 3000 Ω and an equivalent pressure sensitivity of 5μV/V/mmHg ± 10% | Siemens-approved transducers with a resistance of 200 to 3000 Ω and an equivalent pressure sensitivity of 5μV/V/mmHg ± 10% |