10.0 510(k) Summary
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[21 CFR § 807.92(a)1] Contact Information

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[21 CFR § 807.92(a)2] Device Name and Classification

The proprietary name for the two devices are: Corometrics Model 510 Monitor and Corometrics Model 511 Monitor. Common names include: Model 510, Model 511 and Model 510 Series.

As with the predicate device, the modified Model 510 and Model 511 are class II devices. Applicable 21 C.F.R. identifications include: 868.2375, breathing frequency monitor; 870.2300, cardiac monitor; and 870.2700, oximeter.

[21 CFR § 807.92(a)3] Identification of Legally Marketed Devices

Device	Manufacturer (k Number, SE* Date)
Model 510	Corometrics Medical Systems, Inc. (k943308, 7/25/95)
Model 511	Corometrics Medical Systems, Inc. (k942179, 6/2/95)
EdenTec Model 2000W Option H	EdenTec (K871302, 4/20/87 and k905575, 6/20/91)
Nellcor N-180 Pulse Oximeter	Nellcor Puritan Bennett (k913695, 11/13/95)

*SE - Substantial Equivalence

[21 CFR § 807.92(a)4,5] Device Description & Intended Use

The Model 510 Series consists of the Model 510 and the Model 511 monitors. These monitors were originally cleared for monitoring respiration, heart rate, optional pulse oximetry and for detecting central apnea in infants in the home and hospital environments. Both monitors are identical in design with the exception that the Model 511 has a numeric display and the Model 510 does not. This submission identifies the additional adult/pediatric monitoring mode.

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[21 CFR § 807.92(a)6] Predicate Device Comparison of Technological Characteristics

The predicate Model 510 Series (Infant Mode) and the proposed Model 510 Series (with Adult/Pediatric Mode enable) uses the same technology for detecting, measuring, and displaying heart rate and respiration rate (including the detection of central apnea). The Model 510 Series measures heart rate based on a three wire electrocardiograph (ECG). The heart rate is calculated from the lead I signal using the R-R interval on a beat-to-beat basis. The respiration method utilized is transthoracic impedance, using the same three wires as the ECG component. This technology is the same as that of the EdenTec predicate device, for both patient populations.

The pulse oximetry mode is based on spectrophotometry and plethysmography techniques developed by Nellcor Puritan Bennett (NPB). Specifically, the Model 510 Series utilizes the same signal processing board and patient accessories as the NPB N-180 Pulse Oximeter.

[21 CFR § 807.92(b)1] Brief discussion of nonclinical tests

Nonclinical testing that was required to demonstrate substantial equivalence focused on the device changes that were the subject of this 510(k) submission: enabling the adult/pediatric mode via a software change. This software change did not affect the mechanical or electrical performance of the monitor; thus electrical and mechanical testing was required to be retested. Nonclinical testing consisted of: (a) validation of the software change and regression testing of applicable monitor functions/operations; and (b) verification of compliance with applicable requirements of ANSI/AAMI EC-13:1992.

The accuracy of heart rate, respiration rate and percent SpO_2 were verified in the validation and verification phase through the use of a patient simulator. The visual and audible alarm functions (e.g. apnea, heart rate, respiration rate, etc.) were repeatedly verified with pre-defined and random selected limits. Vital operations such as Self-Test functions were also verified. A software Validation Test Plan, derived from the overall system specifications was used to challenge the various system capabilities.

The monitor was tested and found to be in compliance to applicable requirements of ANSI/AAMI EC-13:1992. The applicable requirements to which the monitor was tested include: 3.2.1 Operating Condition, 3.2.2 Overload Protection, 3.2.3 Risk Current (isolated patient connection), 3.2.4 Auxiliary Output Risk Current (isolated patient connection), 3.2.5 Respiration Lead-Off Sensing and Active Noise Suppression Risk Current, 3.2.6 QRS Detection, 3.2.7 Range/Accuracy of Heart Rate Meter, 3.2.8 Alarm System, Alarm Limit Range.

807.92(b)2 Brief discussion of clinical tests
Clinical testing of the adult/pediatric mode was performed as additional verification of the monitor performance in a clinical setting. The primary objective was to assess the accuracy of respiration detection. Subjects monitored in the study were divided into two groups: Group 1 (Pediatric, age 1 - 18 years) or Group 2 (Adult; age 19 years and older). Each patient was dual monitored with the test device and a reference monitor (i.e. nasal airflow). Recordings were independently scored by the principal investigator. Evaluation of the collected data included: comparison of the respiratory rate detection (510 Series vs. nasal airflow); and visual comparison

of cardiac, respiratory and airflow waveforms. An analysis of the results demonstrated that the % true and false positive alarms had considerable variation in relation to the electrode placement. The study population consisted of a representative distribution (62% male, 38% female with ages ranging from 2 to 74 years of age). The correlation between the study monitor and the reference device was consistent with previous findings for the predicate Model 510 Series (infant mode).

807.92(b)3 Conclusions drawn from 807.92(b)1,2

New device testing focused on the software changes required to enable the Adult/Pediatric mode. The specific changes identified in this submission regarded only software and associated labeling changes. It was determined that these changes did not affect the electrical or mechanical performance of the monitor. The original electrical and mechanical performance testing that was submitted with the infant 510(k) submission still applied, and was therefore not repeated.

In summary, the monitor was found to comply with the requirements of the Validation Test Plan and product system specifications. Verification of the monitor performance in clinical testing showed that the correlation between the 510 Series to nasal airflow remain consistent with previous findings for the predicate Model 510 Series (i.e. with infant mode enabled only). These test results along with the labeling and the predicate device comparison of device specifications demonstrate that the modified 510 Series is substantially equivalent to its listed predicate devices.