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510(k) Summary
for
SERVO VENTILATOR 300 AND COMPUTER INTERFACE BOARD

1. **DATE THIS SUMMARY WAS PREPARED**: September 24, 1996

2. **SUBMITTER'S NAME AND ADDRESS**

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4. **DEVICE NAME**

Trade/Proprietary Name:	Servo Ventilator 300 and Computer Interface Board Version 2
Common Name:	Ventilator
Classification Name:	Ventilator, Continuous (Respirator)

5. **PREDICATE DEVICES**

The legally marketed devices to which equivalence is being claimed are:

- Servo Ventilator 300 and Computer Interface Board Version 1, marketed by Siemens-Elema.

6. DEVICE DESCRIPTION

The Servo Ventilator 300 and Computer Interface Version 2 is a modification of the Servo Ventilator 300 and Computer Interface Version 1 which was found Substantially Equivalent on June 26, 1991 (Premarket Notification K902859). These modifications are being made to update the hardware design and to make additional software features available, while retaining the original functionality.

The Servo Ventilator 300 Alarm and Monitoring Module has been modified to eliminate false or otherwise unnecessary alarms by eliminating the "Leakage Alarm" feature, and miscellaneous minor improvements to other alarm functions. This improves ease of use, and has the additional benefit of improving user vigilance when real alarms occur.

The Computer Interface, CI, is an accessory circuit board that interfaces the ventilator to an external information-gathering system, such as a personal computer, via asynchronous serial lines. Information, such as trend data, real time parameter values, and technical information, is transferred to the external system via different commands. The modifications in the Version 2 hardware improve reliability and manufacturing efficiency. The modifications in the Version 2 software allow the user to select from a wider variety of data channels and add the transmission of checksums to ensure data integrity.

7. INTENDED USE

The Siemens Servo Ventilator 300 is intended for general and critical ventilatory care for use with neonatal, infant, pediatric, and adult patients The unit is designed to be used at the bedside and for in-hospital transport. It is not intended for transport use in ambulances or helicopters in the U.S. market.

The intended use of the Computer Interface Board Version 2 is the same as for the Computer Interface Board Version 1. The CI board stores and transmits information about the ventilator to external digital devices via optically isolated serial interfaces.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The hardware modifications to the Servo Ventilator 300 consist of minor changes to circuit design to improve reliability and to facilitate changes in the alarm logic. The redundant nature of the Alarm and Monitoring subsystem requires that both hardware and software be modified simultaneously in order to implement a change to the alarm logic.

The software changes to the Servo Ventilator Alarm and Monitoring Module implement the removal of the "Leakage Alarm" feature, and minor adjustments in other alarm functions. The two circumstances that can trigger the leakage alarm in the predicate device, gross leaks in the breathing circuit and a malfunctioning flow transducer, will also trigger the expired minute volume alarm, so there is no reduction in patient safety from removing this alarm function.

The Servo Ventilator 300 Computer Interface Version 2 is a hardware and software modification to the Servo Ventilator 300 Computer Interface Version 1, which is an accessory to the Servo Ventilator 300 which was found substantially equivalent on June 26, 1991 (Premarket Notification K902859). The hardware design changes improve reliability, increase immunity to interference, and simplify manufacturing by updating the circuit design and incorporating state-of-the-art electronic components. The only hardware modification that affects the hardware requirements specification is the addition of "jumpers" in series with the external control inputs which are used for product test procedures. These jumpers are removed when the device is manufactured to disable functions that are not intended to be available to the user. The software modifications add the transmission of checksums to ensure data integrity and introduce new functions which provide the external data gathering system with an expanded list of data items that can be queried from the Servo Ventilator.

9. NON-CLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The design of the modified Servo Ventilator 300 and Computer Interface Board Version 2 has been thoroughly validated at the unit, integration and system level. Non-clinical tests were conducted of the complete Servo Ventilator 300 with the Computer Interface installed. All alarm conditions were simulated and all output channels were tested by simulating a range of ventilator operating states and noting the outputs from the serial ports using both MS-Windows Terminal program, Version 3.1 and a proprietary program for displaying ventilator parameters (Servo Graphics, Version 1.0). All tests were passed according to criteria that are equal or more stringent than the test criteria which were applied to the predicate device.

10. CONCLUSION

Analysis and testing have shown that the modifications to the Servo Ventilator 300 alarm logic improves the ease of use of the device without adversely affecting patient safety.

Updating the hardware design and expanding the list of data items that can be requested from the Computer Interface Board are changes that are not critical to the intended therapeutic use of the Servo Ventilator 300 and do not adversely affect the safety and effectiveness of the device when used as labeled. The hardware improvements affect the safety and effectiveness of the Servo Ventilator 300 by reducing the risk of ventilator shutdown as a result of component failures on the Computer Interface Board.

Therefore, we conclude that the requirements specifications and validation testing show that the modified device is as safe and effective, and performs as well as or better than the predicate device.