Section 2 - Summary & Certification

Submitter's Name and Address

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Sweden

OCT 14 1997

Official Correspondent

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Contact Person for this Submission

Ms. Ann-Christine Jönsson

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Device Name

Trade/Proprietary Name:	Servo Ventilator 300A
Common Name:	Ventilator
Classification Name:	Ventilator, Continuous (Respirator)

Predicate Device

The legally marketed device to which equivalence is being claimed is:

Siemens Servo Ventilator 300 (K960010)

Device Description

The Servo Ventilator 300A is a modification of the Servo Ventilator 300 which was found Substantially Equivalent on October 25, 1996 (Premarket Notification K960010). The physical differences between the Servo Ventilator 300 and the Servo Ventilator 300A consist of a software change and adding of a new printed circuit board as well as a new switch and two LED's on the front panel.

In the Servo Ventilator 300A a new functionality called Automode has been added, which is a method that, by using functionality from existing breathing modes, allows the patient to better interact with the ventilator. Each controlled mode has a corresponding supported mode. This gives the possibility for the ventilator to react on patient effort - triggering, and lack of effort - apnea. Essentially the ventilator can be set in two states, support or control. Which of these states that are active is determined by a pre-defined algorithm.

Coupled modes:

Volume Control (VC)	⇔	Volume Support (VS)
Pressure Control (PC)	⇔	Pressure Support (PS)
Pressure Regulated Volume Control (PRVC)	⇔	Volume Support (VS)

When Automode is activated and the ventilator is in PC, VC or PRVC, a switch from the controlled breathing pattern to supported will be induced if the patient triggers two consecutive breaths. In the case of apnea lasting longer than 5 seconds for Neonate, 8 seconds for Pediatric or 12 seconds for Adult, the ventilator will switch back to controlled ventilation with the current settings now applicable to the controlled mode.

A possibility for the patient to interrupt the inspiration and initiate an exhalation is added during controlled breaths in Automode PRVC or PC. This change is made to further adapt the ventilation to the patient.

Intended Use

The Servo Ventilator 300A is intended for general and critical ventilatory care for use on Adult, Pediatric, Infant and Neonatal 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 for Servo Ventilator 300A is the same as for the Servo Ventilator 300.

Comparison of Technological Characteristics

The hardware modification, compared to the original Servo Ventilator 300, is that a new knob has been added on the front panel, to make it possible to switch the Automode functionality on and off. If the Automode switch is in the off position, the functionality of the Servo Ventilator 300A is identical to the functionality of the Servo Ventilator 300.

The switching between controlled and supported modes that is done automatically with Automode has always been possible to do manually on the Servo Ventilator 300. For some of the supported modes in Servo Ventilator 300, the Automode functionality improves the safety for the patient, by doing an automatic switch to a controlled mode in case of apnea, instead of just giving an alarm.

Tests Used in Determination of Substantial Equivalence

The design of the Servo Ventilator 300A has been thoroughly validated at the unit, subsystem and system level. All different settings of the new functionality was tested, as well as all the ventilation modes and the complete alarm system. All test were passed according to criteria that are equal or more stringent than the test criteria which were applied to the predicate device.

A clinical test has also been performed to evaluate the automatic switching between controlled and supported ventilation.

Conclusion

Analysis and tests has shown that the new functionality Automode improves the adaptation of the ventilator to the patient needs, as well as the ease of use of the device, without adversely affecting patient safety.

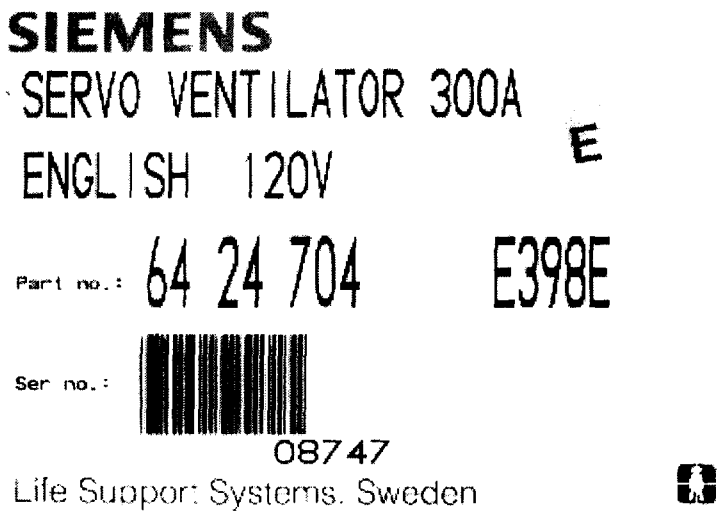
Therefor, we conclude that the requirements specifications and validation testing show that the modified device is as safe and effective, and performs as well or better as the predicate device.

Section 3 - Proposed Labeling

Labeling of the Device

All labeling of the device itself can be found in the mechanical drawings "Mont. Instr" (Mounting Instruction) #60 40 476 E380E and "Paneltryck" (Panel Printing) #64 19 191 E398E, provided as APPENDIX B-1. Other labeling can be found in the accompanying documentation, i.e. the Operating Manual, provided as APPENDIX A-1.

Below is an example of a package label for the Servo Ventilator 300A.



Intended Use Statement

Purpose and function of the Servo Ventilator 300A:

The Servo Ventilator 300A is intended for general and critical ventilatory care. This software and hardware enhancement will adapt the ventilator status to the patient's breathing efforts, by automatic switching between controlled and supported breathing.

The ventilator will deliver controlled or supported breaths to the patient, with either constant flow or constant pressure, using a set oxygen concentration. The operator can choose to either set the desired pressure or the desired minute volume. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings.

Intended Operator:

The Servo Ventilator 300A is intended to be used by Healthcare providers, i.e. Physicians, Nurses and Technicians.

Intended Patient Populations:

The Servo Ventilator 300A is intended to be used on Adult, Pediatric, Infant and Neonatal populations.

Intended Use Environment:

The Servo Ventilator 300A is intended to be used in the environment where patient care is provided by Healthcare Professionals. 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.

Substantial Equivalence:

The enhanced functionality for the Servo Ventilator 300A is equivalent to the Siemens Servo Ventilator 300. The Siemens Servo Ventilator 300 was granted pre-market approval under 510(k) file number K960010.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1997

Ms. Ann-Christine Jönsson
Siemens-Elema AB
Röntgenvägen 2
Solna
SWEDEN

Re: K970839
Servo Ventilator 300A
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: July 19, 1997
Received: July 23, 1997

Dear Ms. Jönsson:

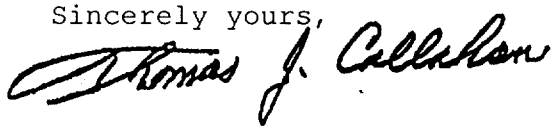
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statment:

510(k) Number (if known):

Device Name: Servo Ventilator 300A

Indications For Use:

Use of the Servo Ventilator 300A is indicated for adult, pediatric or neonatal patient populations in an environment where patient care is provided by Healthcare Professionals (Physician, Nurse, Technician), when the professional determines that a device is required to assist the breathing of the patient. The device can be used both for controlling the entire ventilation for patients without any ability to breathe, as well as for supporting patients with reduced ability.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles C. for MAC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970839

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)