

K960854

510(k) Summary for
Siemens Servo Ultra Nebulizer 345

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1. Date this summary was prepared

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2. Submitter's Name and Address

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4. Device Name

Trade/Proprietary Name: Servo Ultra Nebulizer 345
Common Name: Ultrasonic Nebulizer Accessory to Servo Ventilator 300
Classification Names: (1) Nebulizer
(2) (Accessories to) Ventilator, Continuous (Respirator)

5. Predicate Devices

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

- Microsonic Ultrasonic Nebulizer, marketed by Medisonic U.S.A. Inc.
- Omron NE-U07 Ultra-Air, marketed by Omron Healthcare, Inc.
- Siemens Servo Nebulizer 945

6. Device Description

The Servo Ultra Nebulizer 345 (SUN 345) is an accessory to the Servo Ventilator 300 that is used to nebulize medication during ventilator treatment. An ultrasonic nebulizer similar to those commonly marketed as a component of home "medication inhaler" devices has been adapted for use in the patient circuit of the Servo Ventilator. The ultrasonic nebulizer does not add any gas volume to the circuit, so that readings and settings on the ventilator are unaffected. The SUN 345 medication cup holds 10 ml of liquid, which is nebulized at a rate of 0.3 ml/min at 0.5 l/min gas flow. The mass median diameter of particles is 4.0 μm .

7. Intended Use

The intended use of the Siemens Model 345 Ultra Nebulizer is to nebulize liquid medication for introduction into the patient's airway via an endotracheal tube. It can be used on any patient for whom the use of the Siemens Servo Ventilator 300 is indicated, in any ventilatory mode appropriate for the patient.

8. Comparison of Technological Characteristics

The Servo Ultra Nebulizer 345 works by exciting the medication with ultrasonic energy at a frequency of 2.4 Mhz, as do the Medisonic and Omron products. The Servo Nebulizer 945 uses the jet principal.

The SUN 345 produces particles with a mass median diameter of 4 μm . The Medisonic has particle size of 3-5 μm , and the Omron 1-5 μm .

The SUN 345 has a nebulization rate of 0.5 ml water/min at 1 l/sec gas flow, and 0.3 ml water/min at 0.5 l/sec gas flow. This compares to up to 2 ml/min for the Medisonic and 0.4 ml/min for the Omron.

9. Nonclinical Tests Used in Determination of Substantial Equivalence

The design of the Siemens Model 345 Ultra Nebulizer has been thoroughly validated at the unit and system level. Non-clinical tests were conducted to determine particle size and nebulization rate for various medications and ventilator flow rates. The complete system consisting of the SUN 345 and the Servo Ventilator 300 has been tested to the electrical safety requirements and the Electromagnetic Compatibility requirements of EN 60601.

0. Conclusions From Nonclinical Testing

The testing of the SUN 345 demonstrates that the performance is substantially equivalent to predicate devices cited above.