SALTER LABS

K962879

OCT 22 1996

15. 510(k) Summary

15.1 Purpose:

This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

15.2 Submitter Identification:

Salter Labs
100 W. Sycamore
Arvin, CA 93203

Telephone: (805) 854-3166

Contact Person: James N. Curti

15.3 Date of Summary Preparation:

19, July, 1996

15.4 Name of Device:

15.4.1 Classification Name:

Nebulizer (direct patient interface)

15.4.2 Trade Name:

Nebulizer

15.4.3 Proprietary Name:

Salter Labs Ultramist Nebulizer, 8660 Series

15.5 Identification of Predicate Device:

Salter Labs Hand Held Pneumatic Powered (disposable) Nebulizer Model 8900, which was cleared for marketing by 510(k) No, K870027.

15.6 Description of the Device:

Each of the Salter Labs 8660 Series Nebulizers consists of a Nebulizer Top which is screwed onto a Nebulizer Cup. The bottom of the cup has a fitting to accept a source of nebulizing gas.

Liquids to be nebulized are placed in the nebulizer cup. The top of the nebulizer housing is then applied, and the supply line for the nebulizing gas source is then connected to the bottom of the

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nebulizer cup.

After the pressurized nebulizing gas is applied to the nebulizer, the solution in the cup is nebulized and pushed from the unit in aerosol form that can be inhaled by the patient.

15.7 Intended Use:

The Model 8660 Series Nebulizers have the same intended use as their predicate device, The Salter Model 8900 Nebulizer, which was cleared for marketing by 510(k) No. K870027. The nebulizer is a reusable single patient use device (whereas the 8900 is a disposable single patient use device) which is used where liquids are to be delivered to a patient in an aerosol form. The device is not life-supporting or life-sustaining, nor is it implanted . It does not use software, nor is it sterile, although it must be cleaned or disinfected per the label instructions before reuse. The device is for single patient use. It is intended to be used with accessories, such tubing which is an industry standard device used with nebulizers.

15.8 Difference(s) Between This Device and its Predicate Device:

The Model 8660 Series Nebulizers are the same as their predicate device except:

Each includes an internal reservoir for the aerosol, which eliminates the need for the external tee adapter and reservoir tube

The 8660 Series is reusable on a single patient, whereas the 8900 is a disposable single-use device.

The 8660 series is constructed of different materials to allow autoclaving.

The 8660 Series has different labeling, which includes cleaning and disinfecting instructions.

The 8660 Series includes an inspiratory valve in the nebulizer top.

The 8660 Series includes an expiratory valve in its mouthpiece.

None of these differences has a significant effect on the safety or effectiveness of the device.

15.9 Signature of contact person:

James N. Curti

End of 510(k) Summary

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