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GRZAN

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Guide for OXYGEN CONSERVING DEVICE 510(k) Review

73 BZD 868.5905 Non-continuous Ventilator Class: II

I. DEVICE SPECIFICATIONS

A. Use

1. The labeling should include a statement and description of the types of oxygen sources to be used with the oxygen conserving device (i.e., hospital wall source oxygen, USP bottled oxygen, and oxygen produced by an oxygen concentration device).

2. Prior 510(k)'s have established that the device can be used with an oxygen source for a patient who requires supplemental oxygen for disease states such as Chronic Obstructive Pulmonary Disease (COPD) or Emphysema. Should be used only when nasal oxygen cannula is prescribed.

B. Specification Criteria

1. What are the electrical power source requirements of the device? Does the device operate on wall socket AC only? Is there a battery back-up in case of power failure?

2. What is the maximum pressure that the oxygen source can deliver to the conserving device for functionality? Is the upper limit for pressure specified (i.e., Can be used with oxygen supplies that output up to 25 psi)?

3. What type of valve is used to restrict the flow of oxygen during the expiratory portion of the respiratory cycle? Is the valve normally open or normally closed in the resting position? In case of a device failure of any type, will the valve permit or restrict the flow of oxygen to the patient?

4. Does the Oxygen Conserver have any effect on the normal flow rate from the oxygen source to the patient in the valve open condition?

5. Can the conserver be used with oxygen supply sources that deliver varying flow rates, i.e., in the range of 0.5 to 10 lpm?

6. Does the device contain safeguards against electrical spark generation (i.e., reverse bias diode to restrict current flow after valve solenoid opening or closing or other method)? Will the safeguard protect against ignition of the enhanced oxygen environment? Does the device contain moving metal parts? Are there safeguards against spark generation for these parts?

7. Is the device solid-state controlled and hard wired or does the device contain a microprocessor? Does the microprocessor controlled device conform to the moderate software concern guidance document?

8. Is the sensitivity of the inspiratory effort well outlined and sensitive enough to give an accurate account of inspiration? (approximately 1 cm H_2O negative pressure).

C. Alarms

1. Does the device contain a power failure or low battery alarm?

2. Does the device utilize a flow failure alarm?

3. If the device is software controlled, is there an alarm package for microprocessor failure? Is the design fail-safe; Is there an alarm alarm?

II. LABELING

1. Oxygen conserving devices are prescription devices and must be labeled in conformance to 21 CFR Section 801.109. Both the device and its labeling will bear the prescription legend.

2. Does the device contain the standard warning labels for any device associated with an increased oxygen concentration above 21%?

3. Does the device provide an accurate and complete description of the device and its output parameters?