

SMDA
510(k) Summary

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1.0 Date

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2.0 Submitter

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5.0 Proprietary Device Name

Lifesaver Single Patient Use Manual Resuscitator

6.0 Classification Name

Ventilator, emergency, manual (resuscitator)

7.0 Common Name

Resuscitation Bag or Resuscitator

8.0 Predicate Device

Infant/Pediatric Resuscitation Circuit
Vital Signs, Inc.
K911465

9.0 Device Description

The Hudson RCI Lifesaver Single Patient Use Manual Resuscitator is a disposable, single patient use, medical device which temporarily augments ventilation in patients during ventilatory insufficiency or ventilatory failure. As is the case with the device in the original submission, this modified resuscitator may be used in the hospital, in physician office, out-patient care facilities, extended care facility, home, emergency medical services and patient transport. The only difference between the original device and this modified version is the presence of a pressure monitoring port located on the non-rebreathing valve component of the finished device assembly.

10.0 Intended Use

The Hudson RCI Lifesaver Single Patient Use Manual Resuscitator with pressure monitoring port is disposable medical device intended for use on patients requiring temporary augmentation of ventilation, with or without supplemental oxygen delivery, during episode of acute ventilatory failure or insufficiency, who, because of their weight or other factors, require monitoring of peak inspiratory pressure.

The Hudson RCI Lifesaver Single Patient Use Manual Resuscitator provides a means of temporary ventilation until the patient either regains the ability to spontaneously ventilate, or until other life sustaining measures may be implemented. Resuscitators may also be used as a "back-up" ventilation system in the event of mechanical ventilator failure, or may be used to hyper oxygenate or hyperventilate a patient prior to endotracheal tube suctioning or endotracheal intubation. The pressure monitoring port component of the device permits the monitoring of peak inspiratory pressures in those patients where PIP is a concern.

11.0 Patient Population

The Hudson RCI Lifesaver Single Patient Use Manual Resuscitators may be used on a varying population from neonates to adults. The modified component with the pressure monitoring port will initially be offered on neonate and child versions of the product line. However, the pressure monitoring port may be offered as an option on adult models in the future.

12.0 Comparison of Technological Characteristics

Hudson RCI Lifesaver Single Patient Use Manual Resuscitators with pressure monitoring port are substantially equivalent to the predicate device in design and function.

Both products use a duck-bill valve in their non-rebreathing valve assemblies, and both devices have a pressure monitoring port located prior to the duck-bill valve. Both devices attach the non-rebreathing valve directly onto the ventilation bag, offer three different size resuscitators, and provide oxygen reservoir systems.

Testing of the modified non-rebreathing valve component against the predicate devices similar component to determine the capability of the pressure monitoring port to provide access for measuring peak inspiratory pressures at various settings for ventilatory rates, tidal volumes, compliance and resistance, demonstrated only a slight discrepancy between the two devices. The Hudson RCI pressure monitoring port provided pressure differentials between readings taken at the valve versus readings taken proximal to the patient ranging from 0-3 cm H₂O, while the predicate device provided pressure differential readings of 0-5 cm H₂O. This difference is not considered to be clinically significant.

13.0 Conclusion

Both the Hudson RCI pressure monitoring port and the predicate device pressure monitoring port are able to provide peak inspiratory pressure measurements. Test results have demonstrated that the Hudson RCI modified component is substantially equivalent in safety and effectiveness to the legally marketed predicate device with respect to its intended use.