

K970289

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3.0 Summary of Safety and Effectiveness

The DeVilbiss Model 3650 Compressor / Nebulizer is designed for use on the order of a physician for the treatment of respiratory diseases such as asthma, cystic fibrosis and chronic obstructive pulmonary disease. In terms of function, safety and effectiveness this device is substantially equivalent to other legally marketed compressor / nebulizers commonly used for the treatment of respiratory diseases. The compressor is constructed of materials, both metal and plastic, that are similar or identical to legally marketed devices. The unit is designed and manufactured to comply with electrical and mechanical safety standards applicable to this type of device (Underwriter's Laboratory Standard UL1431, Attachment D).

Used in conjunction with a jet (pneumatic) nebulizer, the system converts liquid medication into an aerosol form that can be inhaled by the patient for the treatment of a variety of respiratory disorders. The DeVilbiss Model 3650 compressor / nebulizer system produces an aerosol output with the majority of the aerosol by mass contained in particles less than 5 microns in diameter (per the requirements of the BSI standard, Attachment E). This aerosol particle size performance is comparable to other legally marketed devices as noted in the Table of Comparison and the Discussion of Similarities and Performance Data (Sections 6.0 & 7.0).

The Table of Comparison and the Performance Evaluations (Sections 6.0 & 7.0) show that in terms of safety and effectiveness, the new DeVilbiss Model 3650 Compressor / Nebulizer is substantially equivalent to legally marketed predicate devices.

Legally Marketed Predicate Devices
DeVilbiss Model 5650
Healthdyne, Inc. 323

510(k) Registration #
K 923888
K 922623