SUNRISE

K020932

JUN 2 8 2002

11.0 510(k) Summary

Submitter's Name:	Sunrise Medical HHG, Inc. Respiratory Products Division 100 DeVilbiss Drive Somerset PA 15501 Ray Hoffman (PH)814-443-7442 (Fax)814-443-7571
Date Prepared:	February 28, 2002
Device Name:	Compressor / Nebulizer FDA Classification CAF
Common or Usual Name:	Compressor / Nebulizer
DeVilbiss Model Number:	3655 Series
Trade Proprietary Name:	DeVilbiss Pulmo-Aide Compact Compressor
Established Registration Number:	DeVilbiss # 2515872
FDA Classification:	Class II

Equivalent Legally Marketed Predicate Devices:

Legally Marketed Predicate Devices	510(k) Registration #
DeVilbiss Model 3650	K 970289

Description of Device:

The DeVilbiss Model 3655 Compressor/Nebulizer is a small, piston-type air compressor, sized to provide the proper flow and pressure sufficient to power jet (pneumatic) nebulizers. 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 and IEC 60601-1).

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When the compressor is used in conjunction with a therapeutic 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 3655 compressor/nebulizer system produces an aerosol output with the majority of the aerosol by mass contained in particles less than 5 microns in diameter.

Statement of Intended Use:

The DeVilbiss compressor / nebulizer Model 3655 includes an AC powered air compressor that provides a source of compressed air for home health care use. The compressor is used in conjunction with a jet (pneumatic) nebulizer to convert certain inhalable drugs into an aerosol form for inhalation by a patient. The device can be used with adult or pediatric patients.

Statement of Safety and Effectiveness:

The DeVilbiss Model 3655 aerosol compressor / nebulizer is equivalent in both function and indications for use to the DeVilbiss Model 3650 aerosol compressor / nebulizer legally marketed predicate device.

The DeVilbiss Model 3655 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. 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

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 3655 compressor / nebulizer system produces an aerosol output with the majority of the aerosol by mass contained in particles less than 5 microns in diameter. 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 4.0 & 5.0).

The Table of Comparison and the Performance Evaluations (Sections 4.0 & 7.0) show that in terms of safety and effectiveness, the new DeVilbiss Model 3655 Compressor / Nebulizer is substantially equivalent to legally marketed predicate devices.

Legally Marketed Predicate Devices	**510(k) Registration #**
DeVilbiss Model 3650	K 970289

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Technological Characteristics:

The DeVilbiss Model 3655 aerosol compressor / nebulizer is equivalent in functional characteristics to the existing legally marketed predicate devices. The devices all utilize an AC motor driven air compressor to provide a source of compressed air for operating a jet (pneumatic) nebulizer. All of the devices are tested and approved to recognized agency safety standards.

Testing performed on the aerosol output and particle size show that the new DeVilbiss Model 3655 is substantially equivalent to the existing legally marketed predicate devices and that all of these devices will produce a similar aerosol treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2002

Sunrise Medical HHG, Inc.
c/o Ned Devine
Entela, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K020932
Devilbiss Model 3655 Compressor/Nebulizer
Regulation Number: 21 CFR 868.5630 and 21 CFR 868.6250
Regulation Name: Nebulizer and Portable Air Compressor
Regulatory Class: II (two)
Product Code: 73 CAF and 73 BTI
Dated: June 14, 2002
Received: June 18, 2002

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: (if known): K020932 ~~Not yet assigned~~

Device Name: DeVilbiss Model 3655 Compressor / Nebulizer

Indications For Use:

The DeVilbiss compressor / nebulizer Model 3655 includes an AC powered air compressor that provides a source of compressed air for home health care use. The compressor is used in conjunction with a jet (pneumatic) nebulizer to convert certain inhalable drugs into an aerosol form for inhalation by a patient. The device can be used with adult or pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K020932

X Prescription use -OR- ___ Over-the-counter use