

APR 21 2000

K993492

**510(k) Summary**

**Submitter's Name:** Sunrise Medical HHG, Inc.  
100 DeVilbiss Drive  
Somerset PA 15501  
Frank Clementi  
814-443-7474

**Date Prepared:** October 7, 1999

**Device Name:** Nebulizer FDA Classification CAF

**Common or Usual Name:** Jet Nebulizer

**DeVilbiss Model Number:** Nebulizer Model 800

**Trade Proprietary Name:** N/A Model number only.

**Established Registration Number:** 2515872

**FDA Classification:** Class II

**Equivalent Legally Marketed Predicate Devices:**

<b>Legally Marketed Predicate Device</b>	<b>510(k) Registration #</b>
Sunrise Medical Model 700	K952249
Pari LC Plus	K894555
Pari PariJet	K896984

**Description of Device:**

The Sunrise Medical Model 800 Series jet nebulizer is a reusable hand held, small volume jet nebulizer. The nebulizer is designed for use in conjunction with a compressed gas source such as the Sunrise Medical Pulmo-Aide Model 5650 Compressor (FDA 510(k) Registration # K923888), Sunrise Medical Pulmo-Mate Model 4650 Compressor (FDA 510(k) Registration # K931015) or Sunrise Medical Pulmo-Aide LT Model 3650 Compressor (FDA 510(k) Registration # K970289). The nebulizer & compressor system is used on the order of a physician to treat various respiratory problems. The nebulizer converts the liquid medication into a fine aerosol mist, which can be inhaled for home respiratory therapy. This allows the medication to be deposited at the affected areas of the patient's airway.

The Sunrise Medical Model 800 Series jet nebulizer is designed to offer high respirable aerosol output for the patient. The nebulizer is intended as a long term usage nebulizer (approximately 1 year) similar to other reusable nebulizers that are currently being marketed by competitors of Sunrise Medical such as the Pari LC Plus and Pari Jet permanent nebulizers manufactured by Pari of Germany and distributed here in the U.S.

Accessories include a triggering system to shut off airflow to the nebulizer to conserve medication between breaths.

**Statement of Intended Use:**

The Sunrise Medical Model 800 Series jet nebulizer is designed for use in conjunction with a compressed gas source such as the Sunrise Medical Pulmo-Aide Model 5650 Compressor (FDA 510(k) Registration # K923888), Sunrise Medical Pulmo-Mate Model 4650 Compressor (FDA 510(k) Registration # K931015) or Sunrise Medical Pulmo-Aide LT Model 3650 Compressor (FDA 510(k) Registration # K970289). The system is used on the order of a physician to treat various respiratory problems. The nebulizer converts the liquid medication into a fine aerosol mist, which can be inhaled for home respiratory therapy. This allows the medication to be deposited at the affected areas of the patient's airway.

The Sunrise Medical Model 800 Series jet nebulizer is designed to offer high respirable aerosol output for the patient. The nebulizer is intended as a long term usage nebulizer (approximately 1 year) similar to other reusable nebulizers that are currently being marketed by competitors of DeVilbiss such as the Pari LC Plus and Pari Jet permanent nebulizers manufactured by Pari of Germany and distributed here in the U.S.

The target patient population for this device is comprised of both children and adults suffering from asthma, bronchitis, emphysema, and other respiratory disorders. The device is to be used by the patient only on the order of a physician in conjunction with prescribed medication(s).

The intended environment of use is in the home with AC powered compressors or for portable use with DC/battery powered compressors.

**Technological Characteristics:**

The Sunrise Medical Model 800 Nebulizer is equivalent in functional characteristics to the existing legally marketed predicate devices. The devices all utilize a compressed air source for operation.

Testing performed on the aerosol output and particle size show that the new Sunrise Medical Model 800 Nebulizer is substantially equivalent to the existing legally marketed predicate devices and that all of these devices will produce a similar aerosol treatment.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Frank Clementi  
Sunrise Medical HHG Inc.  
Respiratory Products Division  
Dba DeVilbiss Health Care  
100 DeVilbiss Drive  
P.O. Box 635  
Somerset, PA 15501-0635

Re: K993492  
Sunrise Medical Model 800 Nebulizer  
Regulatory Class: II (two)  
Product Code: CAF  
Dated: January 21, 2000  
Received: January 24, 2000

Dear Mr. Clementi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

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for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

*Joanna A. Weberhausen for,*

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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

Device Name: Sunrise Medical Model 800 Nebulizer

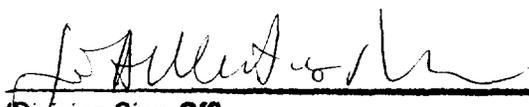
**Indications For Use:**

The system is used on the order of a physician for the treatment of asthma, bronchitis and other respiratory diseases. The nebulizer converts the liquid medication into a fine aerosol mist which can be inhaled for home respiratory therapy. This allows the medication to be deposited at the affected areas of the patients airway.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K993492