



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 03 2002

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

Re: K020900  
Model 9200D Heated Humidifier  
Regulation Number: 868.5450  
Regulation Name: Respiratory Gas Humidifier  
Regulatory Class: II (two)  
Product Code: 73 BTT  
Dated: May 20, 2002  
Received: May 21, 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.

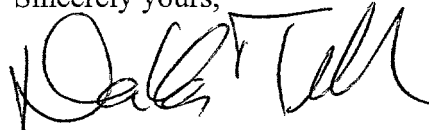
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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

510(k) Number (if known): K020900

Device Name DeVilbiss Model 9200D Heated Humidifier

**Indications For Use:**

The DeVilbiss Heated Humidifier System, consisting of the 9100D DeVilbiss CPAP Humidifier and the 9200 DeVilbiss Humidifier Heater, is to be used in conjunction with most positive airway pressure devices that require humidity to be added to the circuitry.

The DeVilbiss Heated Humidifier System is not intended to be used with auto-adjusting CPAP devices unless the labeling for the CPAP machine states that the CPAP machine will function in auto-set mode when used with the 9200 heated humidifier system. The heated humidifier system may adversely affect the operation of certain CPAP machines that have automated pressure setting.

The DeVilbiss Heated Humidifier System is for use in the home environment and is to be used only on the order of a physician. The humidifier can be used with CPAP and Bilevel devices, which have a maximum operating pressure of 20 cm H<sub>2</sub>O. The humidifier can also be used with noninvasive ventilation devices that have a maximum operating pressure of 40 cmH<sub>2</sub>O.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K020900