

K963349

13 1997

510(k) SUMMARY STATEMENT

Submitter: DeVilbiss Health Care, Inc.
1200 East Main Street
P.O. Box 635
Somerset, Pa 15501-0635 USA

Contact: Matt Smith
814-443-7531
814-443-7571 FAX

Date of 510(k) Submittal: August 26, 1996

Classification Name: Pump, Nebulizer, Electrically Powered

Common Name: Compressor used for nebulization and humidification

Proprietary Name: 8650D

Equivalent to Device: Allied Healthcare/Timeter PCS414

Description of Device:

The DeVilbiss 8650D Compressor is a portable AC powered air compressor that will act as an air source to operate a pneumatic nebulizer. The device has an internal cooling fan to allow continuous use operation. It uses a metal housing with sound barrier foam to provide a low noise level.

Intended Use of Device:

The DeVilbiss 8650D is used with a pneumatic nebulizer to administer humidified air or medication into the airways to treat respiratory disorders. The device is intended for home health care and institutional use. Users of this device are adult and pediatric patients with tracheostomies or suffer from asthma, cystic fibrosis, and chronic obstructive pulmonary disease.

Performance Testing:

The DeVilbiss 8650D was tested for pressure and flow output, sound pressure level, temperature rise, and shipping performance. *and electromagnetic compatibility.*

Agency Approvals:

The DeVilbiss 8650D will meet UL-544 Standard for Safety, Medical and Dental Equipment.

Conclusion:

The results of the above testing do not indicate any safety and effectiveness concerns as compared to the Allied Healthcare PCS 414.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 13 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Matt Smith
DeVilbiss Health Care, Inc.
1200 East Main Street
P.O. Box 635
Somerset, Pennsylvania 15501-0635

Re: *K963349
DeVilbiss 8650D
Regulatory Class: II (two)
Product Code: 73 BTI
Dated: May 18, 1997
Received: May 19, 1997

Dear Mr. Smith:

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 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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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) 594-4646. 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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K963349/A1

510(k) Number (if known): K963349

Device Name: DeVilbiss Health Care, Inc. 8650D Compressor

Indications For Use:

The 8650D will be used as the air source to nebulize sterile water to provide humidification to patients with tracheostomies.

The 8650D may also be used to nebulize medications in the treatment of Asthma, Cystic Fibrosis, and chronic obstructive pulmonary disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Justin D. Timesdale
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K963349

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)