K091919

SEP 2 8 2009

Section 5.0 510(k) Summary

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission:		DeVilbiss Healthcare 100 DeVilbiss Drive Somerset, PA 15501
FDA registration number of the manufacturer of the new device:		2515872
Official contact person for all correspondence:		Betty Lou Miller Regulatory Affairs Coordinator DeVilbiss Healthcare 100 DeVilbiss Drive Somerset, PA 15501 Phone: 814-443-7602 Fax: 814-443-7571 Email: betty.miller@devilbisshc.com
Date Prepared:		
Device Name:		DeVilbiss Intellipap/SleepCube S
Proprietary name of new device:		DeVilbiss Intellipap/SleepCube S
Common or usual name of the device:		DeVilbiss S
DeVilbiss Model Number		DV55 S Series
Classification of the predicate device:		Class II
Classification of new device:		Class II
Classification Panel:		Anesthesiology
Panel Code:		BZD
CFR Regulation Number:		21 CFR 868.5905 Ventilator, non-continuous respirator
Predicate Device Name(s) and 510(k) number(s):		Resmed VPAP ST - K080131 DeVilbiss 9055 Bilevel - K032056 DeVilbiss Intellipap - K071689

Description of Device:

The role of the product from a patient's point of view is to provide a continuous source of bilevel positive airway pressure for the treatment of sleep apnea. Positive airway pressure is applied to the oropharynx to act as a pneumatic splint to prevent the collapse of the pharyngeal muscle, which occludes the patient airway during sleep. Bilevel units are used over conventional CPAP units due to high pressures and/or patient intolerance to continuous pressure, making exhalation difficult.

The DeVilbiss Bilevel S product will replace the 9055D in the sleep product line as well as provide a new product offering. The product will have a reduced manufactured cost, primarily derived from reduced material costs and improved engineering design associated with the existing Intellipap/SleepCube product platform. The market has dictated a need for lower cost and smaller sized bilevel units as well as improved functionality such as manually adjustable inhale/exhale triggering sensitivity.

The triggering sensitivity overall must be increased as much as possible to be competitive with other bilevel devices currently available. Automatic and manual inhale/exhale trigger sensitivity is to be provided to allow the clinician to customize trigger parameters for specific operating conditions. The DeVilbiss Intellipap/SleepCube Bilevel S product is not intended to meet the needs for the "ventilator" market, which necessitates features such as alarms, higher operating pressures and other ventilator specific functions

Comparison of Device Technological Characteristics to Predicate Devices:

The submitted DeVilbiss Bilevel S has the following similarities to those which previously received 510(k) concurrence:

- Has the same intended use,
- Uses the same operating principle,
- Incorporates the same basic Bilevel modes and settings,
- Incorporates similar materials

Statement of Intended Use:

The DeVilbiss Intellipap/SleepCube Model DV55 S Series is intended for use in treating OSA in spontaneously breathing patients 30 Kg and above by means of application of positive air pressure. The Device is to be used in home and clinical environments.

Non-Clinical Testing:

This device has been tested to appropriate ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. The DeVilbiss DV55 S Series Bilevel CPAP was designed and tested according to guidance outlined in:

1. FDA's Draft Reviewer Guidance for Premarket Notification Submissions – Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993); and
2. FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005),

As suggested by FDA's November 1993 publication entitled "Reviewer Guidance for Premarket Notification Submissions – Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices" the DeVilbiss Bilevel S/ST was tested in accordance with the applicable voluntary standards. The DeVilbiss Bilevel S/ST met the required performance criteria and functioned as intended.

See Section 16.7 Validation, Verification Testing, Section 17.0 Electromagnetic Compatibility and Electrical Safety, Section 18.0 Performance Testing and Attachment B.

Statement of Safety and Effectiveness:

Analysis of comparison of design, function and features of the DeVilbiss Bilevel S to the Resmed VPAP ST (K080131), DeVilbiss 9055 Bilevel (K032056) and DeVilbiss Intellipap (K071689), together with the results of testing demonstrates the device to be substantially equivalent to the predicate devices in terms of meeting performance criteria and functioning as intended.

Conclusion:

The DeVilbiss Intellipap/SleepCube Bilevel S is substantially equivalent to the predicate device listed in this Summary and the device, as changed, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 2 8 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Betty Lou Miller
Regulatory Affairs Coordinator
Sunrise Medical
100 DeVilbiss Drive
Somerset, Pennsylvania 15501

Re: K091919
Trade/Device Name: DeVilbiss IntelliPAP/SleepCube Model DV55 S Series CPAP
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: June 26, 2009
Received: June 30, 2009

Dear Ms. Miller:

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.

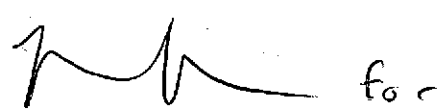
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

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

Device Name: DeVilbiss IntelliPAP/SleepCube Model DV55 S Series CPAP

Indications For Use:

The DeVilbiss IntelliPAP/SleepCube Model DV55 S Series is intended for use in treating OSA in spontaneously breathing patients 30 Kg and above by means of application of positive air pressure. The Device is to be used in home and clinical environments.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for L. Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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