DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 4, 2014

DeVilbiss Healthcare LLC
Ms. Betty Miller
Regulatory/Compliance Manager
100 DeVilbiss Drive
Somerset, PA 15501

Re: K140880
Trade/Device Name: DeVilbiss DV5MB Smartlink II System
Regulation Number: 21 CFR 868.5905
Regulation Name: Ventilator, Non-Continuous Respirator
Regulatory Class: II
Product Code: BZD
Dated: July 1, 2014
Received: July 3, 2014

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: (if known): K140880

Device Name: **DeVilbiss DV5MB Smartlink II System**

The DeVilbiss DV5MB SmartLink II System can only be used in conjunction with the DeVilbiss DV51, DV53, DV54, DV55, DV56, and DV57 Series CPAP Systems for follow up of obstructive sleep apnea in patients weighing above 30 kg on nasal CPAP therapy. The system is to be used in home and healthcare 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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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 LLC 100 DeVilbiss Drive Somerset, PA 15501
FDA registration number of the manufacturer of the new device:		2515872
Official contact person for all correspondence:		Betty Miller Regulatory/Compliance Manager DeVilbiss Healthcare LLC 100 DeVilbiss Drive Somerset, PA 15501 Phone: 814-443-7606 Fax: 814-443-7575 Email: betty.miller@devilbisshc.com
Date Prepared:		03/21/2014
Device Name:		DeVilbiss DV5MB SmartLink II
Proprietary name of new device:		DeVilbiss DV5MB SmartLink II System
Common or usual name of the device:		SmartLink II
DeVilbiss Model Number		DV5MB
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):		DeVilbiss DV5M SmartLink System (K082209)

Description of Device:

The proposed DeVilbiss DV5MB SmartLink II System is an accessory to DeVilbiss IntelliPAP DV5x Series CPAPs, models DV51, DV53, DV54, DV55, DV56 and DV57. The proposed DeVilbiss DV5MB SmartLink II System connects physically and electrically to a DV5x Series CPAP for the purpose of collecting usage and performance data from the CPAP for subsequent download to PC software for storage, viewing and reporting.

The proposed DeVilbiss DV5MB SmartLink II System is identical to the predicate device with the addition of a Bluetooth Wireless connection. The Bluetooth radio used is a complete Bluetooth module with built in antenna and Bluetooth v2.1 + EDR. The maximum output power of the Bluetooth radio is +2.5 dBm, has a maximum range of 10 meters. The DeVilbiss DV5MB SmartLink II System wireless feature can be used in the home or in a healthcare setting.

Comparison of Device Technological Characteristics to Predicate Devices:

The proposed DeVilbiss DV5MB SmartLink II Module has the following similarities to those which previously received 510(k) concurrence:

- Has the same intended use
- Uses the same operating principle
- Incorporates similar materials

The only modifications that were made are:

- Added Bluetooth Wireless communication interface

Comparison of Similarities and Differences:

Feature	Predicate Device: DeVilbiss DV5M SmartLink System (K082209)	Modified Device: DeVilbiss DV5MB SmartLink II System	Nature of Change
Intended Use Statement	The DeVilbiss DV5M SmartLink System in conjunction with a DeVilbiss CPAP Unit is intended for use in treating obstructive sleep apnea in patients 30 Kg and above. The system is to be used in home and healthcare environments.	The DeVilbiss DV5MB SmartLink II System in conjunction with a DeVilbiss CPAP Unit is intended for use in treating obstructive sleep apnea in patients 30 Kg and above. The system is to be used in home and healthcare environments.	Same as predicate.

Feature	Predicate Device: DeVilbiss DV5M SmartLink System (K082209)	Modified Device: DeVilbiss DV5MB SmartLink II System	Nature of Change
Indications for Use Statement	The DeVilbiss DV5M SmartLink System can only be used in conjunction with the DeVilbiss DV51, and DV54 Series CPAP Systems for follow up of obstructive sleep apnea in patients weighing above 30 kg on nasal CPAP therapy	The DeVilbiss DV5MB SmartLink II System can only be used in conjunction with the DeVilbiss DV51, DV53, DV54, DV55, DV56, and DV57 Series CPAP Systems for follow up of obstructive sleep apnea in patients weighing above 30 kg on nasal CPAP therapy. The system is to be used in home and healthcare environments.	Add compatibility with additional DV5x Series CPAP models. No impact on safety or effectiveness.
Compliance recording	Records 3 years of "while breathing" ON/OFF compliance, 120 days of Daily Performance, Rx change, approximately 72 hours of Oximetry, and Fault logs	Records 3 years of "while breathing" ON/OFF compliance, 120 days of Daily Performance, Rx change, approximately 72 hours of Oximetry, and Fault logs	Same as predicate.
User interface	The DeVilbiss DV5M SmartLink Module is designed to mechanically and electrically attach to a DV5x series CPAP. The module uses the onboard Keypad/ Display of the DV5x CPAP as the user interface. The user interface is located on the top of the DV5x CPAP and consists of a 6 button keypad and a 2x16 LCD Display.	The DeVilbiss DV5MB SmartLink II System is designed to mechanically and electrically attach to a DV5x series CPAP. The module uses the onboard Keypad/ Display of the DV5x CPAP as the user interface. The user interface is located on the top of the DV5x CPAP and consists of a 6 button keypad and a 2x16 LCD Display.	Same as predicate.
Oximeter Function	The DeVilbiss DV5M SmartLink Module uses an optional Nonin oximeter to log SpO2 and Pulse Rate at 4-second intervals.	The DeVilbiss DV5MB SmartLink II System uses an optional Nonin oximeter to log SpO2 and Pulse Rate at 4-second intervals.	Same as predicate.

Feature	Predicate Device: DeVilbiss DV5M SmartLink System (K082209)	Modified Device: DeVilbiss DV5MB SmartLink II System	Nature of Change
Software Function	The SmartLink software is used to display data as it is recorded from the module. The software stores data in a data based structure and has querying and reporting functionality.	The SmartLink software is used to display data as it is recorded from the module. The software stores data in a data based structure and has querying and reporting functionality. (See Section 16.0 software section)	Improvements to user interface and performance. No impact on safety or effectiveness.
Remote settings change function	CPAP Settings can be changed through an SD card, settings are programmed through SmartLink Desktop software.	CPAP Settings can be changed through an SD card, settings are programmed through SmartLink Desktop software.	Same as predicate.
Remote control function	Wired RS232 connection to a distance of up to 200 feet.	Wired RS232 connection to a distance of up to 200 feet. Wireless Bluetooth connection to a distance of up to 33 feet.	Added Bluetooth wireless communication, operates same as wired RS232 connection. No impact on safety or effectiveness.
Means of Data Transfer	Memory card or wired RS232 connection	Memory card or wired RS232 connection	Same as predicate.
Environmental Specifications	Operating temperature: 5 to +40 °C. Operating humidity range: 0 to 95% R.H. non condensing Storage temperature range: -40 to +70 °C Storage humidity range: 0 to 95% R.H. non-condensing	Operating temperature: 5 to +40 °C. Operating humidity range: 0 to 95% R.H. non condensing Storage temperature range: -40 to +70 °C Storage humidity range: 0 to 95% R.H. non-condensing	Same as predicate.
Power Requirements	The DeVilbiss DV5M SmartLink Module is not equipped with an on-board power supply. It only receives its power (12 VDC) from the DV5x Series CPAP device during operation.	The DeVilbiss DV5MB SmartLink II System is not equipped with an on-board power supply. It only receives its power (12 VDC) from the DV5x Series CPAP device during operation.	Same as predicate.

Feature	Predicate Device: DeVilbiss DV5M SmartLink System (K082209)	Modified Device: DeVilbiss DV5MB SmartLink II System	Nature of Change
510(k) Product Code	BZD (Ventilator, non-continuous (respirator))	BZD (Ventilator, non-continuous (respirator))	Same as predicate.
Materials comparison			
Enclosure	GE Plastics Cycoloy CX2244ME PC/ABS Blend FR30U – Meets UL94 V-0 flame retardant spec. (P/N: 420-0200-004)	GE Plastics Cycoloy CX2244ME PC/ABS Blend FR30U – Meets UL94 V-0 flame retardant spec. (P/N: 420-0200-004)	Same as predicate.

Statement of Intended Use:

The DeVilbiss DV5MB SmartLink II System can only be used in conjunction with the DeVilbiss DV51, DV53, DV54, DV55, DV56, and DV57 Series CPAP Systems for follow up of obstructive sleep apnea in patients weighing above 30 kg on nasal CPAP therapy. The system is to be used in home and healthcare environments.

Non-Clinical Testing:

This device has been tested to appropriate ISO and IEC standards and other applicable requirements passing all test protocols. The proposed DeVilbiss DV5MB SmartLink II has been fully tested to demonstrate compliance with the applicable sections of the following standards:

1. IEC 60601–1–1:2000 Medical Electrical Equipment—Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems
2. IEC 60601–1–2:2007 Ed 3.0 Medical Electrical Equipment—Part 1: General Requirements for Safety; Electromagnetic Compatibility Requirements and Tests
3. IEC 60601-1-4:2000 Consol. Ed. 1.1, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1.
4. ISO 14971:2012 Medical devices - Application of risk management to medical devices
5. EN55011:2007 Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurements
6. IEC 529 (1989): Classification of Degrees of Protection Provided by Enclosures
7. IEC 68 (1988): Environmental Testing

8. ISTA Procedure 3A Package –Products for Parcel Delivery System Shipments 70kg (150lb) or less

9. FCC Regulation 47 CFR Part 15 Radio Frequency Devices, Class B

Additional design considerations were applied based on published guidance and draft guidance documents from FDA:

1. FDA Reviewer Guidance for Premarket Notification Submissions (Anesthesiology and Respiratory Device Branches, November 1993)

2. DRAFT FDA Guidance - Design Considerations for Devices Intended for Home Use Dec 12- 2012

3. DRAFT FDA Guidance_Cybersecurity in Medical Devices 6-13-13

4. FDA Guidance - Radio Frequency Wireless Technology in Medical Devices Aug 14-2013

The proposed DeVilbiss DV5MB SmartLink II System in conjunction with a DeVilbiss CPAP Unit meets the required performance criteria and functioned as intended. See Section 12.0 and Section 9.0.

Clinical Testing:

No clinical testing or clinical performance evaluations were conducted on the proposed DeVilbiss DV5MB SmartLink II relating to clinical studies to demonstrate substantial equivalence to the predicate device.

Conclusion:

The proposed DeVilbiss DV5MB SmartLink II System is substantially equivalent to the predicate DV5M SmartLink Compliance Module (K082209) and the device, as changed, does not raise any new issues of safety and effectiveness.

Analysis of comparison of design, function and features of the proposed DeVilbiss DV5MB SmartLink II System to the predicate DV5M SmartLink Compliance Module (K082209), together with the results of testing demonstrate the device to be substantially equivalent to the predicate devices in terms of meeting performance criteria and functioning as intended.