DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 21, 2016

DeVilbiss Healthcare, LLC
c/o Paul Dryden
President, ProMedic, Inc.
100 Devilbiss Drive
Somerset, Pennsylvania 15501

Re: K152810
Trade/Device Name: DeVilbiss DV6WM Wireless Modem
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 20, 2015
Received: December 22, 2015

Dear Paul Dryden:

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" (21 CFR 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.
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Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152810

Device Name

DeVilbiss DV6WM Wireless Modem

Indications for Use *(Describe)*

The DeVilbiss Healthcare DV6WM Wireless Modem is intended to be used as a data collection tool for DeVilbiss IntelliPAP Series with SmartLink II Bluetooth module, IntelliPAP2, and DeVilbiss Blue Series CPAPs for patients in a home or healthcare environment. It is not intended to be used as a diagnostic tool.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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
Official contact person for all correspondence:		Betty Miller Regulatory/Compliance Manager Phone: 814-443-7606 Fax: 814-443-7575
Date Prepared:		December 20, 2015
Device Name:		DeVilbiss DV6WM Wireless Modem
Proprietary name of new device:		DeVilbiss DV6WM Wireless Modem
Common or usual name of the device:		ventilator, non-continuous (respirator)
DeVilbiss Model Number		DV6WM-NA, DV6WM-EU, DV6WM-UK
Classification		Class II
Panel Code:		73 BZD
CFR Regulation Number:		21 CFR 868.5905
Predicate Device Name(s) and 510(k) number(s):		K082209 – DeVilbiss DV5M Smartlink System K093684 Resmed EasyCare Online

Description of Device:

The proposed DeVilbiss DV6WM Wireless Modem is an accessory to a DeVilbiss CPAP machine. The proposed device provides automatic wireless telemetry of CPAP usage and performance data to a healthcare provider. Predicate devices DeVilbiss DV5M Smartlink System (K082209) and Resmed EasyCare Online (K093684) operate by the same basic principal of transferring CPAP data from a therapy device to a PC program for storing and reporting patient usage and machine performance. Predicate device Resmed EasyCare Online (K093684) is used for comparison of data transfer through a cellular data network.

The proposed DeVilbiss DV6WM Wireless Modem is similar in size, shape and functionality to the predicate with the following modifications

- Bluetooth wireless communication
- Cellular wireless communication
- Rechargeable Lithium Polymer battery power

Indications for Use:

The DeVilbiss Healthcare DV6WM Wireless Modem is intended to be used as a data collection tool for DeVilbiss IntelliPAP Series with SmartLink II Bluetooth module, IntelliPAP2, and DeVilbiss Blue Series CPAPs for patients in a home or healthcare environment. It is not intended to be used as a diagnostic tool.

Comparison of Device Technological Characteristics to Predicate Devices:

The proposed DeVilbiss DV6WM Wireless Modem has the following similarities to those which previously received 510(k) concurrence:

- Has the same intended use
- Uses the same operating principle

Modifications that were made:

- Bluetooth wireless communication
- Cellular wireless communication
- Rechargeable Lithium Polymer battery power

Comparison of Similarities and Differences:

Characteristics	Predicate Device: Resmed EasyCare Online (K093684)	Predicate Device: DeVilbiss DV5M SmartLink System (K082209)	Modified Device: DeVilbiss DV6WM Wireless Modem	Nature of Change
Indications for Use Statement	EasyCare Online is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been transmitted from the patient's flow generator located in the home to the care giver. EasyCare Online also provides remote settings capabilities. It is intended to be used by Clinicians in conjunction with ResMed compatible flow generators.	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 not intended to be used as a tool for diagnosis of obstructive sleep apnea (OSA) or related disorders. It is intended to be used to follow up the progress of a patients previously diagnosed with OSA or related disorders treated with nasal CPAP. The system is to be used in home and clinical environments.	The DeVilbiss Healthcare DV6WM Wireless Modem is intended for use as an accessory to DeVilbiss IntelliPAP Series with SmartLink II Bluetooth module, IntelliPAP2, and DeVilbiss Blue Series CPAPs for patients in a home or healthcare environment.	Similar to predicate. no impact on safety or effectiveness
Operating Principle	Device reads data recorded and stored in the Resmed S9 or higher Series CPAP, encodes the data and transfers data to a secure data server. Data is viewed using an on-line data management and report generator web portal.	Device records data from a DeVilbiss DV5 Series CPAP while the CPAP is operating. Internal storage of recorded data is transferred to SmartLink Desktop software via SD card and stored in a local database. SmartLink Desktop software creates reports of CPAP usage and performance.	Device reads data recorded and stored in the DV6 Series CPAP, encodes the data and sends to a secure data server. Data is downloaded into SmartLink Desktop software from secure data server and stored in a local database. SmartLink Desktop software creates reports of CPAP usage and performance.	Similar to predicate. no impact on safety or effectiveness
Operating Modes	Acts as a data transfer device, transfers data from Resmed S9 CPAP to a secure data server.	1. Records data from CPAP, 2. Transfers data to SmartLink Desktop software via SD card.	Acts as a data transfer device. Three modes of operation: 1. Wake, talking to CPAP, reads recorded usage data from CPAP 2. Wake, talking to server, transfers CPAP data to a secure data server 3. Sleep, low power mode, waiting for next scheduled call time	Similar to predicate. no impact on safety or effectiveness
510(k) Product Code	BZD (Ventilator, non-continuous (respirator))	BZD (Ventilator, non-continuous (respirator))	BZD (Ventilator, non-continuous (respirator))	Same as predicate
Power Requirements	Powered from host CPAP	Powered from host CPAP	Powered by internal rechargeable Lithium Polymer battery	Change to internally powered device no impact on safety or effectiveness
Compliance Monitoring	Transfers data recorded and stored in the CPAP wirelessly to a secure data server	Records 3 years of "while breathing" ON/OFF compliance, 120 days of Daily Performance, Rx change, approximately 72 hours of Oximetry, and Fault logs	Transfers data recorded and stored in the CPAP wirelessly to a secure data server	Similar to predicate. no impact on safety or effectiveness
User interface	Shows info on host CPAP LCD display	Shows info on host CPAP LCD display	Shows status info on host CPAP display On proposed device: three LED status indicators for battery, Bluetooth and GSM (cellular); One pushbutton to initiate a test call.	Change to indicate new functions. no impact on safety or effectiveness

Characteristics	Predicate Device: Resmed EasyCare Online (K093684)	Predicate Device: DeVilbiss DV5M SmartLink System (K082209)	Modified Device: DeVilbiss DV6WM Wireless Modem	Nature of Change
Remote settings change function	Can change CPAP prescription settings through Wireless Modem from EasyCare Online Software	Can change CPAP prescription settings through SD Card from SmartLink Desktop Software	Can change CPAP prescription settings through Wireless Modem from SmartLink Desktop Software	Similar to predicate. no impact on safety or effectiveness
Operating Temperature Range	Operating Temperature: +5° to +35° C (+41° to +95° F)	Operating Temperature: +5 to +40 °C. (+41˚F to +104˚F)	Operating Temperature: +5 °C to +40 °C (+41˚F to +104˚F)	Same as predicate.
Operating Humidity Range	Relative Humidity: 15 to 95% (non-condensing)	Relative Humidity: 0 to 95% (non-condensing)	Relative Humidity: 15 % to 93 % (non-condensing)	
Storage Temperature Range	Storage Temperature: -20° to 60°C (-4° to 140° F) Relative Humidity: 15 to 95% (non-condensing)	Storage Temperature: - 40°C to + 70°C (-40 to +158 °F) Relative Humidity: 0% to 95% (non-condensing)	Storage Temperature: - 25°C to + 70°C (-13 to +158 °F) Relative Humidity: 15% to 93% (non-condensing)	
Operating atmospheric pressure range	101 to 77 kPa (0 - 2286 m / 0 - 7500 ft)	101 kPa to 74 kPa Sea level to 9,000 feet (0 to 2743 m)	700 hPa to 1060 hPa (~9800 ft to ~ 1400ft below sea level)	
Shock and Vibration	Not published	Unit shall be able to withstand a drop from a height of 30” IEC 68 Environmental Testing ASTM D-4169 Testing of Shipping Containers	Unit shall be able to withstand a drop from a height of 30” IEC 68 Environmental Testing ASTM D-4169 Testing of Shipping Containers	Same as predicate.
IEC 60601-1 Classification	Type of Protection Against Electric Shock: Class II Equipment Degree of Protection Against Electric Shock: Type BF Applied Part Degree of Protection against Ingress of Water (device & AC power supply): Drip Proof, IPX1 Mode of Operation: Continuous Electrical	Type of Protection Against Electric Shock: Class II Equipment Degree of Protection Against Electric Shock: Type BF Applied Part Degree of Protection against Ingress of Water (device & AC power supply): Drip Proof, IPX1 Mode of Operation: Continuous Electrical	Type of Protection Against Electric Shock: Internally Powered ME Equipment Degree of Protection Against Electric Shock: N/A, No applied part Degree of Protection against Ingress of Water (device & AC power supply): Drip Proof, IP21 Mode of Operation: Non-Continuous	Change in classification to internally powered device, no applied parts no impact on safety or effectiveness
Standards			IEC 60601-1 EN ISO 17510-1 EN 60601-1-2 RTCA/DO-160 section 21, category M	
Dimensions	39.6mm x 54.1mm x 125.0mm	3.9” H x 3.1” W x 1.4” D (9.9cm H x 7.9cm W x 3.6cm D)	4.4”H x 3”W x 1”D (11.2cm x 7.6cm x 2.5cm)	
Weight	< 100 g	0.30 lbs. (0.14 Kg)	0.35 lbs. (158.8 g)	

Discussion of Substantial Equivalence and Differences:

Indications for Use

Similar to predicate device DeVilbiss DV5M SmartLink System (K082209). The proposed DeVilbiss DV6WM Wireless Modem is intended to be used as a data collection tool for DeVilbiss IntelliPAP Series with SmartLink II Bluetooth module, IntelliPAP2, and DeVilbiss Blue Series CPAPs and is not intended to be used as a diagnostic tool. Although the method of data retrieval is different, the purpose of collecting data is the same.

Operating Principle

Similar to predicate device Resmed EasyCare Online (K093684). The proposed DeVilbiss DV6WM Wireless Modem operates as a wireless data transfer device, similar to the predicate Resmed EasyCare Online (K093684). Both devices use GSM cellular telephone technology to send data recorded by the patient's CPAP to a remote data server for access by a healthcare provider. The proposed DeVilbiss DV6WM Wireless Modem uses a wireless link to the patient's CPAP device whereas the predicate Resmed EasyCare Online (K093684) physically and electrically attaches to the patient's CPAP device. The physical separation of the proposed DeVilbiss DV6WM Wireless Modem allows the user to locate the modem where it can get a sufficient cellular signal to connect to the remote data server, and still be in Bluetooth range of the patient's CPAP device. The proposed DeVilbiss DV6WM Wireless Modem completes a data transfer once per day.

Operating Modes

Similar to predicate device Resmed EasyCare Online (K093684). The proposed DeVilbiss DV6WM Wireless Modem has three modes of operation; 1) Wake, reading data from a CPAP, 2) Wake, sending data to secure data server, 3) Low Power Sleep. The proposed DeVilbiss DV6WM Wireless Modem is normally in a low power sleep mode. The proposed DeVilbiss DV6WM Wireless Modem wakes from low power sleep mode by either user pressing the Test Call button or at a scheduled call time. When the proposed DeVilbiss DV6WM Wireless Modem wakes to begin a call cycle, it searches for new Bluetooth devices in range, searches for the target device and processes any new pair requests. Data is read from any paired CPAP devices in range, up to ten devices. After all CPAP data has been read, the Bluetooth radio is switched off and the GSM cellular radio is switched on. The proposed DeVilbiss DV6WM Wireless Modem proceeds to find cellular service, contact the secure data server and upload data read from the CPAPs to the secure data server. The secure data server receives and checks the data integrity and responds to the proposed DeVilbiss DV6WM Wireless Modem that the data was received or has errors. If the data was received without errors, the modem clears data on the CPAP. If the data was received with errors, the modem does not clear data on the CPAP so it is available for the next call. The proposed DeVilbiss DV6WM Wireless Modem cannot be contacted through the cellular phone system, it only makes outgoing calls, and it does not receive calls.

The predicate device Resmed EasyCare Online (K093684) wireless modem device attached to a host Resmed CPAP and is powered by the host CPAP. The wireless modem sends CPAP data to a secure data server. The data is stored in an online data base and viewed online using a web browser and login credentials.

Power Requirements
The proposed DeVilbiss DV6WM Wireless Modem is internally powered by a rechargeable Lithium Polymer (LiPo) battery. The internal LiPo battery is certified to IEC 62133 and UN 38.3, as required by IEC 60601-1 3rd Edition. The LiPo battery allows placement of the modem where it can place cellular calls while in Bluetooth range of the target CPAP.

The predicate devices Resmed EasyCare Online (K093684) and DeVilbiss DV5M SmartLink System (K082209) are physically and electrically attached to the host CPAP device, receiving power from the host CPAP device.

Compliance Monitoring
Similar to predicate device Resmed EasyCare Online (K093684). The proposed DeVilbiss DV6WM Wireless Modem reads data recorded by the host CPAP and transfers the data to a secure data server. The proposed DeVilbiss DV6WM Wireless Modem does not record data and only stores data temporarily during transfer to the secure data server. The predicate device Resmed EasyCare Online (K093684) performs the same function, transferring data recorded by the host CPAP to a secure data server.

User interface
Changed to indicate new functions on proposed device. The proposed DeVilbiss DV6WM Wireless Modem user interface consists of three status LEDs and one pushbutton. The status LEDs indicate status of battery and activity of Bluetooth and GSM (cellular) radio. The proposed DeVilbiss DV6WM Wireless Modem sends status information to a DeVilbiss IntelliPAP2/DeVilbiss Blue Series CPAP during a call sequence. The status information tells the user the battery charge level, Bluetooth signal strength and cellular signal strength. It also indicates the modem serial number and number of days since the last time data was sent to the server. DeVilbiss IntelliPAP Series CPAPs do not display modem status information, this information is available in patient records and reports in DeVilbiss SmartLink Desktop Software.

Functions of the predicate device DeVilbiss DV5M SmartLink System (K082209) that display usage summary information are built into the DV6x Series CPAP.

Remote settings change function
Similar to predicate device Resmed EasyCare Online (K093684) and predicate device DeVilbiss DV5M SmartLink System (K082209). The predicate device Resmed EasyCare Online (K093684) accommodates a similar method of updating CPAP settings. A healthcare provider can modify the CPAP settings on the EasyCare Online web interface. The Resmed wireless modem receives the setting update from the EasyCare Online secure data server and applies them to the patient's CPAP.

The proposed DeVilbiss DV6WM Wireless Modem accommodates wireless prescription settings updates in the same manner that the predicate device DeVilbiss DV5M SmartLink System (K082209) accommodates prescription setting updates via SD card. The healthcare provider modifies CPAP settings for the patient's assigned CPAP device within SmartLink Desktop software. When saving the setting changes, the SmartLink Desktop software provides 3 ways to update settings on the patient's CPAP device; 1) direct wired connection of CPAP to PC, 2) SD card transfer, 3) Wireless Modem. Options 1) and 2) are part of predicate device DeVilbiss DV5M SmartLink System (K082209). Option 3) is new for the wireless modem, settings are sent to the secure data server and relayed to the wireless modem that is associated with the patient's CPAP serial number. When the modem makes a connection to the CPAP, the settings are updated by the modem and verified. New settings are sent back to the secure data server and a notification is posted for the patient's CPAP serial number that the new settings were applied. The setting update is acknowledged in SmartLink Desktop software on the next download form the secure data server for the healthcare provider to verify that the patient's device has been updated.

Operating Humidity Range
Similar to predicate device DeVilbiss DV5M SmartLink System (K082209). The proposed DeVilbiss DV6WM Wireless Modem complies with requirements IEC 60601-1-11 Medical Devices intended for Home Use. The operating humidity range is more narrow and within the range of the predicate device DeVilbiss DV5M SmartLink System (K082209)

Storage Temperature Range
Changed storage temperature range to comply with IEC 60601-1-11. The proposed DeVilbiss DV6WM Wireless Modem complies with requirements IEC 60601-1-11 Medical Devices intended for Home Use. The storage temperature range is more narrow and within the range of the predicate device DeVilbiss DV5M SmartLink System (K082209)

Operating atmospheric pressure range
Changed atmospheric pressure range to comply with IEC 60601-1-11. The proposed DeVilbiss DV6WM Wireless Modem complies with requirements IEC 60601-1-11 Medical Devices intended for Home Use. The atmospheric pressure range is broader than the predicate device DeVilbiss DV5M SmartLink System (K082209).

Dimensions
The proposed DeVilbiss DV6WM Wireless Modem is similar in size to the predicate device DeVilbiss DV5M SmartLink System (K082209).

Weight
The proposed DeVilbiss DV6WM Wireless Modem is similar in weight to the predicate device DeVilbiss DV5M SmartLink System (K082209).

Performance Testing

Non-Clinical Testing:

This device has been tested to appropriate ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. The proposed DeVilbiss DV6WM Wireless Modem was designed and tested to demonstrate compliance with the applicable sections of the following standards:

1. AAMI / ANSI ES60601-1:2005/(R)2012
2. IEC 60601-1-2:2007 Ed. 3.0,
3. IEC 60601-1-11:2010 Ed. 1.0 + Corrigendum 1.0 (4-2011)
4. FCC Regulation 47 CFR Part 15 Radio Frequency Devices, Class B
5. Wireless Standards
    - FCC Part 15
    - Industry Canada RSP-100
    - European wireless standard RTTE directive 1999/5/EC

Human usability validation was conducted with lay users and clinical users to focus on critical and essential tasks as per analysis of user tasks, and evaluation of use reports for similar devices. Any harm that could result from task failures is described in the usability report. Subjective assessments from all participants, particularly in the case of task failures, were collected and analyzed as part of the usability validation.

Clinical Testing:

No clinical testing was necessary to demonstrate the safety and effectiveness of the proposed DV6WM Wireless Modem.

Statement of Safety and Effectiveness:

Analysis of comparison of design, function and features of the proposed DV6WM Wireless Modem to the predicates DV5M SmartLink System (K082209) and Resmed EasyCare Online (K093684), 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.

Conclusion:

The test methods used are the similar to those submitted in the original predicate device submission, updated to reflect new versions of standards and FDA guidance. The proposed DeVilbiss DV6WM Wireless Modem meets all applicable FDA recognized consensus standards. Based on these results, the proposed device, as changed, is substantially equivalent to the following predicate devices: DeVilbiss DV5M SmartLink System (K082209) and Resmed EasyCare Online (K093684) and does not raise any new issues of safety and effectiveness.