DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 18, 2015

DeVilbiss Healthcare, LLC
Betty Miller
Regulatory/compliance Manager
100 DeVilbiss Drive
Somerset, PA 15501

Re: K143677
Trade/Device Name: DeVilbiss Intellipap2/DeVilbiss BLUE
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (Ippb)
Regulatory Class: Class II
Product Code: BZD
Dated: August 19, 2015
Received: August 20, 2015

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" (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.
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): K143677

Device Name: DeVilbiss Intellipap2/DeVilbiss BLUE
Indications For Use:

The DeVilbiss Intellipap2/DeVilbiss BLUE Series is intended for use in treating OSA in spontaneously breathing patients 30 Kg (66 lbs) and above by means of application of positive air pressure. The Device 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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:		December 23, 2014
Device Name:		DeVilbiss Intellipap2/DeVilbiss BLUE
Proprietary name of new device:		DeVilbiss Intellipap2/DeVilbiss BLUE
Common or usual name of the device:		DV63 Series and DV64 Series
DeVilbiss Model Number		DV63 Series Standard Plus and DV64 Series AutoAdjust/AutoPlus
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-continuos respirator
Predicate Device Name(s) and 510(k) number(s):		DeVilbiss Intellipap DV5 Series cleared under K071689 and Respironics, Inc, Remstar Auto A-Flex HT cleared under K113068

Description of Device:

The proposed DeVilbiss Intellipap2/DeVilbiss BLUE are devices for treating obstructive sleep apnea by means of applied airway pressure. Predicates devices DeVilbiss IntelliPAP DV5 Series (K071689), and Respironics, Inc, Remstar Auto A-Flex HT (K113068) operate by the same basic principal of creating pressurized air that is delivered to the patient's airway by a nasal or oral-nasal mask. The devices maintain a set pressure, prescribed by a physician, at the patient's mask for flow rates up to approximately 100 L/m.

The proposed DeVilbiss Intellipap2/DeVilbiss BLUE is similar in size, shape and functionality to the predicate with the following modifications

- Bluetooth wireless communication
- PulseDose Humidity option
- New Respiratory event detection algorithm
- Serial Communication was changed from RS232 serial to USB serial
- An encoded method of prescription setting change, SmartCode Rx

Predicate device Respironics, Inc, Remstar Auto A-Flex HT (K113068) is used for comparison of respiratory event detection.

Comparison of Device Technological Characteristics to Predicate Devices:

The proposed DeVilbiss Intellipap2/DeVilbiss BLUE have the following similarities to those which previously received 510(k) concurrence:

- Has the same intended use,
- Use the same operating principle,
- Incorporates similar materials, and
- Is manufactured and packaged using similar materials and processes.

Modifications that were made:

- Bluetooth wireless communication
- PulseDose Humidity option
- New Respiratory event detection algorithm
- Serial Communication was changed from RS232 serial to USB serial
- An encoded method of prescription setting change, SmartCode Rx

Comparison of Similarities and Differences:

Feature	Predicate Device: Respironics A-Flex HT (K113068)	Predicate Device: DeVilbiss DV53 Standard Plus CPAP, DeVilbiss DV54 Auto CPAP (K071689)	Modified Device: DeVilbiss Intellipap2/DeVilbiss BLUE	Remarks:
Statement of Intended Use	The Remstar Auto A-Flex HT delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patiente weighing over 30kg (66 lbs. It is for use in the home or hospital/institutional environment	The DeVilbiss IntelliPAP/SleepCube CPAP Pro (Model DV53 Series) and AutoAdjust (Model DV54 Series) are 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.	The DeVilbiss Intellipap2/DeVilbiss BLUE Series is intended for use in treating OSA in spontaneously breathing patients 30 Kg (66 lbs) and above by means of application of positive air pressure. The Device is to be used in Home and Healthcare Environments.	Similar to predicates Patient population is the same. Condition treated (OSA) is the same. References to institutional, clinical, and healthcare environments are all considered to be the same environment. No impact on safety or effectiveness

Feature	Predicate Device: Respironics A-Flex HT (K113068)	Predicate Device: DeVilbiss DV53 Standard Plus CPAP, DeVilbiss DV54 Auto CPAP (K071689)	Modified Device: DeVilbiss Intellipap2/DeVilbiss BLUE	Remarks:
Operating Principle	The CPAP machine pressurizes room air and applies the pressurized air to the user's airway through the hose and nasal mask. Breathing the pressurized air flow keeps the airway open, preventing the user from experiencing breaks in breathing while sleeping.	The CPAP machine pressurizes room air and applies the pressurized air to the user's airway through the hose and nasal mask. Breathing the pressurized air flow keeps the airway open, preventing the user from experiencing breaks in breathing while sleeping.	The CPAP machine pressurizes room air and applies the pressurized air to the user's airway through the hose and nasal mask. Breathing the pressurized air flow keeps the airway open, preventing the user from experiencing breaks in breathing while sleeping.	Same as predicate.
Operating Modes	CPAP AutoAdjust	CPAP AutoAdjust	CPAP AutoAdjust	Same as predicate.
510(k) Product Code	BZD (Ventilator, non-continuous (respirator))	BZD (Ventilator, non-continuous (respirator))	BZD (Ventilator, non-continuous (respirator))	Same as predicate.

Feature	Predicate Device: Respironics A-Flex HT (K113068)	Predicate Device: DeVilbiss DV53 Standard Plus CPAP, DeVilbiss DV54 Auto CPAP (K071689)	Modified Device: DeVilbiss Intellipap2/DeVilbiss BLUE	Remarks:
Respiratory Event Detection	Obstructive Apnea, Central Apnea, Hypopnea, Flow Limitation, Periodic Breathing, RERA, Snoring Leak	Apnea, Hypopnea, Snoring, Exhale Puffing Leak	Obstructive Apnea, Central Apnea, Hypopnea, Flow Limitation, Periodic Breathing, RERA, Snoring, Exhale Puffing Leak	Similar to predicates. Added Central Apnea, Flow Limitation, Periodic Breathing and RERA to DeVilbiss predicate No impact on safety or effectiveness
Heated Humidifier	Optional heated humidifier, connects to CPAP electrically and pneumatically	Optional heated humidifier, connects to CPAP electrically and pneumatically	Optional heated humidifier, connects to CPAP electrically and pneumatically	Same as predicate.
PulseDose humidifier option	Optional Heated Tube for use with heated humidifier to reduce rainout in patient tube	Optional heated humidifier, connects to CPAP electrically and pneumatically	Optional PulseDose humidifier module, connects to heated humidifier electrically and pneumatically to reduce rainout in patient tube	Similar to predicate. PulseDose humidifier option reduces rainout, similar to heated tube. No impact on safety or effectiveness

Feature	Predicate Device: Respironics A-Flex HT (K113068)	Predicate Device: DeVilbiss DV53 Standard Plus CPAP, DeVilbiss DV54 Auto CPAP (K071689)	Modified Device: DeVilbiss Intellipap2/DeVilbiss BLUE	Remarks:
Oximeter Function	No oximeter option available	The DeVilbiss DV53 Standard Plus CPAP, DeVilbiss DV54 Auto CPAP uses the DeVilbiss DV5M SmartLink Compliance Module (K082209) to connect an optional Nonin oximeter to log SpO2 and Pulse Rate at 4-second intervals. Not for diagnostic purposes.	The modified DeVilbiss Intellipap2/DeVilbiss BLUE connects wirelessly (Bluetooth) to an optional Nonin Model 3150 WristOx2 oximeter (K102350) to log SpO2 and Pulse Rate at 1-second intervals. Not for diagnostic purposes.	Similar to predicate. Records SpO2 and Pulse Rate from Nonin Oximeter, validated change to wireless connection. No impact on safety or effectiveness
Data Transfer	SD Card Wireless Modem (via Encore Anywhere)	SD Card RS232 Serial Interface	SD Card USB Serial Interface	Similar to predicate. Change to USB serial interface, validated communication No impact on safety or effectiveness

Feature	Predicate Device: Respironics A-Flex HT (K113068)	Predicate Device: DeVilbiss DV53 Standard Plus CPAP, DeVilbiss DV54 Auto CPAP (K071689)	Modified Device: DeVilbiss Intellipap2/DeVilbiss BLUE	Remarks:
Remote settings change function	CPAP Settings can be remotely changed through Encore Anywhere software via Wireless Modem	CPAP Settings can be remotely changed through SmartLink Desktop software via SD card transfer	CPAP Settings can be remotely changed through SmartLink Desktop software via SD card transfer. CPAP Settings can be remotely changed through SmartLink Desktop software via SmartCode Rx feature	Similar to predicate. SD card setting updates same as predicate. SmartCode Rx setting updates validated. No impact on safety or effectiveness
Operating Temperature / Humidity Range	Operating Temperature: 5° to 35° C (41° to 95° F) Relative Humidity: 15 to 95% (non-condensing)	Operating Temperature: +5 to +40 °C. (+41˚F to +104˚F) Relative Humidity: 0 to 95% (non-condensing)	Operating Temperature: +5 °C to +40 °C (+41˚F to +104˚F) Relative Humidity: 15 % to 93 %, (non-condensing)	Similar to predicate. Changed operating relative humidity range to comply with IEC 60601-1-11 No impact on safety or effectiveness

Feature	Predicate Device: Respironics A-Flex HT (K113068)	Predicate Device: DeVilbiss DV53 Standard Plus CPAP, DeVilbiss DV54 Auto CPAP (K071689)	Modified Device: DeVilbiss Intellipap2/DeVilbiss BLUE	Remarks:
Power Requirements	AC Input Power: 100 – 240 VAC, 50/60 Hz, 2.1 A DC Input Power: 12 VDC, 5.0 A	AC Input Power: 100 – 240 VAC, 50/60 Hz, 0.65 A DC Input Power: 12 VDC, 5.0 A	AC Input Power: 100 – 240 VAC, 50/60 Hz, 1.25 A DC Input Power: 12.5 VDC, 5.2 A	Similar to predicate. Same AC input voltage range. DC input requirement slightly higher. No impact on safety or effectiveness passes IEC 60601-1
Materials comparison				
Enclosure	Not Published	GE Plastics Cycoloy CX2244ME PC/ABS Blend FR30U – Meets UL94 V-0 flame retardant spec. (P/N: 420-0200-004)	Sabic PC Lexan HP1R 8H8D331 Bright White, Meets UL94 V-0 flame retardant spec.	Similar to predicate. Same flame rating, different material and color. No impact on safety or effectiveness meets the UL Flame Rating

Statement of Intended Use:

The DeVilbiss Intellipap2/DeVilbiss BLUE Series is intended for use in treating OSA in spontaneously breathing patients 30 Kg (66 lbs) and above by means of application of positive air pressure. The Device is to be used in Home and Healthcare Environments.

Non-Clinical Testing:

This device has been tested to appropriate ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. DeVilbiss Intellipap2/DeVilbiss BLUE Series was designed and tested to demonstrate compliance with the applicable standards.

Verification Activities to demonstrate the performance, effectiveness and safety include:

Controls and indicators
Controls, display and user interface have been verified to function as intended. Application of usability was applied to the design per IEC 60601-1-6 and IEC 62366 (excluding section D4.3.1).

Performance
The performance of the CPAP and Heated Humidifier with PulseDose module has been verified to function as intended and meets the requirements of ISO 17510-1 Sleep Apnea Breathing Therapy Equipment.

Materials
Materials of the device and components have been verified to provide the required level of safety and strength. Materials in the medical gas path have been tested for biocompatibility and air purity to verify that gas pathway is biocompatible. The materials utilized in the design do not raise any new issues of safety and effectiveness.

Safety Evaluation
Safety has been verified to meet the requirements of IEC 60601-1 (Medical Electrical Equipment—Part 1: General Requirements for Safety) and has been designed following ISO 14971 Medical devices - Application of Risk Management to Medical Devices.

Electromagnetic Compatibility
Electromagnetic Compatibility has been tested and verified to meet the requirements of IEC 60601-1-2 (Medical Electrical Equipment – Part 1-2 Electromagnetic Compatibility) and FDA Draft Reviewer Guidance for Premarket Notification Submissions (1993).

Mechanical Stress
Mechanical stress has been tested and verified to meet the requirements of FDA Reviewer Guidance for Premarket Notification Submissions (1993), IEC 60068-2-6, IEC 60068-2-27 and IEC 60068-2-64.

Transportation
Transportation shipping and storage has been tested and verified to meet the requirements of ISTA Procedure 3A: Packaged-Products for Parcel Delivery.

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

Clinical Testing:

Clinical testing was performed to validate the respiratory event detection and pressure change decisions made by the proposed device during therapy. A single-center, prospective, controlled study was designed to validate improvements to the predicate software algorithm in the DeVilbiss AutoAdjust CPAP flow generator, a device that is already FDA-cleared under K071689 and in use in the U.S. The revised algorithm is intended to improve precision of treatment and phenotyping of residual disease.

Subjects with a sleep apnea diagnosis who were on stable therapy enrolled in a one-night PSG titration study. DeVilbiss AutoAdjust CPAP device with revised algorithm was compared to hand-scored PSG to determine whether the machine results are equivalent to hand scores. Each subject acted as their own control for assessing accuracy of sleep event analysis and prescribed CPAP pressure.

The primary objective of the study was to demonstrate effectiveness of therapy provided by the DeVilbiss AutoAdjust CPAP device as reported by an expert human reviewer. A total of 28 subjects, with a diagnosis of moderate to severe sleep apnea on stable therapy, completed the study. 57% of subjects were male and 43% were female. Subject ages ranged from 27 to 75 years, with a mean age of 54.0 years. Twenty six of the subjects completing the study were diagnosed with Obstructive Sleep Apnea, and 2 with Mixed Sleep Apnea. Three (3) adverse events were reported for one subject. All the events consisted of mild digestive distress and were unrelated to the study device. No safety concerns were raised in the course of the study.

Statement of Safety and Effectiveness:

Analysis of comparison of design, function and features of the proposed DeVilbiss Intellipap2/DeVilbiss BLUE Series to the predicates DeVilbiss IntelliPAP DV5 Series cleared under K071689, and substantially equivalent to Respironics, Inc, Remstar Auto A-Flex HT cleared under K113068, 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 Intellipap2/DeVilbiss BLUE Series 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.