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

September 9, 2016

ResMed Ltd
c/o Ms. Larissa D'andrea
Director, Government and Regulatory Affairs
ResMed Corp
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K160822
Trade/Device Name: S9 VPAP Adapt, VPAP Adapt, AirCurve 10 ASV
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: August 10, 2016
Received: August 11, 2016

Dear Ms. D'andrea:

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

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
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)*

Device Name
S9 VPAP ADAPT

Indications for Use *(Describe)*
The S9 VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. The S9 VPAP Adapt is intended for home and hospital use.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*

Device Name
AirCurve 10 ASV

Indications for Use *(Describe)*
The AirCurve 10 ASV device is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

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

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

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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)*

Device Name
VPAP Adapt

Indications for Use *(Describe)*
The VPAP Adapt is indicated for the treatment of patients weighing more than 66lb (30kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. The VPAP Adapt is intended for home and hospital use.

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

☒ 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 – S9 VPAP Adapt

Required	By Section 807.92 (c)
Date Prepared	18 March, 2016
Owners Name	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153, Australia
Submitter	Jasjit Baveja + 61 2 8884 1518 (Phone) + 61 2 8884 2000 (FAX) Jasjit.baveja@resmed.com.au
Official Contact	Larissa D'Andrea Director, Government & Regulatory Affairs ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123 +1 858 836 6837 (Phone) +1 858 836 5519 (Fax) Larissa.D'Andrea@resmed.com
Product codes	73 BZD
Class	II
Classification Reference	21 CFR 868.5905, Product Code 73 BZD
Common/Usual Name	Non continuous ventilator (IPPB)
Proprietary Name	S9 VPAP Adapt
Predicate device(s)	S9 VPAP Adapt (K102586)

Reason for submission

This 510(k) is being submitted as a labelling change for the addition of the following contraindication:

ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF $\leq$ 45%) and moderate to severe predominant central sleep apnea.

This contraindication is supported by SERVE-HF, which was a randomized, parallel, event-driven, international multi-center study in 1325 patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF≤45%) and moderate to severe predominant central sleep apnea. The study investigated the effects of adding ASV to guideline-based medical management on survival and cardiovascular outcomes. The addition of ASV did not improve outcomes and showed an increased risk of cardiovascular mortality despite effective control of central sleep apnea.

Intended Use

The S9 VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. The S9 VPAP Adapt is intended for home and hospital use.

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate devices.

- Same intended use
- Same operating principle
- Similar technologies
- Same manufacturing process

ResMed has determined that the new device has not altered the safety and effectiveness of CPAP treatment for patients with Obstructive Sleep Apnoea (OSA), central and/or mixed apneas, or periodic breathing who weigh more than 66 lb (>30 kg). The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notification Submissions (November 1993)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

As this was a labelling change only, no further clinical or non-clinical testing was required to show substantial equivalence to the predicate device S9 VPAP Adapt (K102586)

The new device is as safe and effective as the predicate device.

Device description

The S9 VPAP Adapt is identical to the predicate device S9 VPAP Adapt (K102586), using a blower based positive pressure system with an integrated heated humidifier and heater controller. The device platform is identical to the S9 VPAP Adapt (K102586) and contains a Micro-processor controlled blower system that generates controlled positive airway pressure between 3-25 cmH_2O as required to maintain an “air splint” for effective treatment of OSA. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier.

The S9 VPAP ADAPT is a flow generator device designed to provide adaptive servo-ventilation therapy (ASV) to stabilize a patient's ventilation during sleep. The device continually measures the patient's instantaneous ventilation,

and calculates a target ventilation based on to the patient's recent average. It then adjusts the degree of pressure support to servo-control the patient's ventilation to at least equal the target ventilation.

Therapy modes contained in the S9 VPAP Adapt are:

- CPAP mode;
- CPAP with EPR
- Auto Servo Ventilation (ASV)

Therapy modes come from the predicate S9 VPAP Adapt (K102586).

The functional characteristics of the S9 VPAP Adapt system include all the clinician and user friendly features of the predicate device.

Characteristic	S9 VPAP Adapt (K102586)	New Device (S9 VPAP Adapt)	Comments
Indication for use	The S9 VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. The S9 VPAP Adapt is intended for home and hospital use.	The S9 VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. The S9 VPAP Adapt is intended for home and hospital use.	Equivalent *Only labeling change to include contraindication*
Location of use	Hospital/Home	Hospital/Home	Equivalent
Pressure Range and Treatment Modes			
	4-20 cm H_2O (CPAP) 3-25 cm H_2O (ASV)	4-20 cm H_2O (CPAP) 3-25 cm H_2O (ASV)	Equivalent:
RAMP Settings	➢ User selected as "Off" to 45 minutes in 5 minute increments ➢ Max Ramp time set at clinician's discretion	➢ User selected as "Off" to 45 minutes in 5 minute increments ➢ Max Ramp time set at clinician's discretion	Equivalent
System Components	➢ Flow generator ➢ Integrated humidifier (5i) ➢ Mask, air tubing and heated tubing	➢ Flow generator ➢ Integrated humidifier (5i) ➢ Mask, air tubing and heated tubing	Equivalent
Power supply	100-240V, 50-60Hz	100-240V, 50-60Hz	Equivalent
Flow generator weight	1.7lb	1.7lb	Equivalent
Dimensions H x W x D (inches)	Flow generator unit: 3.4 x 5.5 x 6.0	Flow generator unit: 3.4 x 5.5 x 6.0	Equivalent

Characteristic	S9 VPAP Adapt (K102586)	New Device (S9 VPAP Adapt)	Comments
Supplemental oxygen	Labeled for use with supplemental oxygen	Labeled for use with supplemental oxygen	Equivalent

Conclusion

The S9 VPAP Adapt is substantially equivalent to the predicate device, S9 VPAP Adapt (K102586).

510(k) Summary – VPAP Adapt

Required	By Section 807.92 (c)
Date Prepared	18 March, 2016
Owners Name	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153, Australia
Submitter	Jasjit Baveja + 61 2 8884 1518 (Phone) + 61 2 8884 2000 (FAX) Jasjit.baveja@resmed.com.au
Official Contact	Larissa D'Andrea Director, Government & Regulatory Affairs ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123 +1 858 836 6837 (Phone) +1 858 836 5519 (Fax) Larissa.D'Andrea@resmed.com
Product codes	73 BZD
Class	II
Classification Reference	21 CFR 868.5905, Product Code 73 BZD
Common/Usual Name	Non continuous ventilator (IPPB)
Proprietary Name	VPAP Adapt
Predicate device(s)	VPAP Adapt (K113801)

Reason for submission

This 510(k) is being submitted as a labelling change for the addition of the following contraindication:

ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF $\leq$ 45%) and moderate to severe predominant central sleep apnea.

This contraindication is supported by SERVE-HF, which was a randomized, parallel, event-driven, international multi-center study in 1325 patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF≤45%) and moderate to severe predominant central sleep apnea. The study investigated the effects of adding ASV to guideline-based medical management on survival and cardiovascular outcomes. The addition of ASV did not improve outcomes and showed an increased risk of cardiovascular mortality despite effective control of central sleep apnea.

Indication for Use

The VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. The VPAP Adapt is intended for home and hospital use

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate devices.

- Same intended use
- Same operating principle
- Similar technologies
- Same manufacturing process

ResMed has determined that the new device has not altered the safety and effectiveness of CPAP treatment for patients with Obstructive Sleep Apnoea (OSA), central and/or mixed apneas, or periodic breathing who weigh more than 66 lb (>30 kg). The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notification Submissions (November 1993)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

As this was a labelling change only, no further clinical or non-clinical testing was required to show substantial equivalence to the predicate device VPAP Adapt (K113801).

The new device is as safe and effective as the predicate device.

Device Description

The VPAP Adapt is identical to the predicate device (K113801), using a blower based positive pressure system with an integrated heated humidifier and heater controller. The device platform is identical to the VPAP Adapt (K113801) and contains a Micro-processor controlled blower system that generates controlled positive airway pressure between 3-25 cmH_2O as required to maintain an “air splint” for effective treatment of OSA. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier.

The VPAP Adapt is a flow generator device designed to provide adaptive servo-ventilation therapy (ASV) to stabilize a patient's ventilation during sleep. The device continually measures the patient's instantaneous ventilation, and

calculates a target ventilation based on to the patient's recent average. It then adjusts the degree of pressure support to servo-control the patient's ventilation to at least equal the target ventilation.

Therapy modes contained in the VPAP Adapt are

- CPAP
- ASV
- ASVAuto

The CPAP and ASV therapy modes come from the VPAP Adapt (K113801).

The functional characteristics of the VPAP Adapt system includes all the clinician and user friendly features of the predicate device.

Characteristic	VPAP Adapt (K113801)	New Device (VPAP Adapt)	Comments
Indication for use	The VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.	The VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.	Equivalent *Only labeling change to include contraindication*
Location of use	Hospital/Home	Hospital/Home	Equivalent
Pressure Range and Treatment Modes			
	4-20 cm H_2O (CPAP) 3-25 cm H_2O (ASV) 3-25 cm H_2O (ASVAuto)	4-20 cm H_2O (CPAP) 3-25 cm H_2O (ASV) 3-25 cm H_2O (ASVAuto)	Equivalent:
RAMP Settings	➢ User selected as "Off" to 45 minutes in 5 minute increments ➢ Max Ramp time set at clinician's discretion	➢ User selected as "Off" to 45 minutes in 5 minute increments ➢ Max Ramp time set at clinician's discretion	Equivalent
System Components	➢ Flow generator ➢ Integrated humidifier (5i) ➢ Mask, air tubing and heated tubing	➢ Flow generator ➢ Integrated humidifier (5i) ➢ Mask, air tubing and heated tubing	Equivalent
Power supply	100-240V, 50-60Hz	100-240V, 50-60Hz	Equivalent
Flow generator weight	1.7lb	1.7lb	Equivalent
Dimensions H x W x D (inches)	Flow generator unit: 3.4 x 5.5 x 6.0	Flow generator unit: 3.4 x 5.5 x 6.0	Equivalent

Characteristic	VPAP Adapt (K113801)	New Device (VPAP Adapt)	Comments
Supplemental oxygen	Labeled for use with supplemental oxygen	Labeled for use with supplemental oxygen	Equivalent

Conclusion

The VPAP Adapt is substantially equivalent to the predicate devices, VPAP Adapt (K113801).

510(k) Summary – AirCurve 10 ASV

Required	By Section 807.92 (c)
Date Prepared	18 March, 2016
Owners Name	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153, Australia
Submitter	Jasjit Baveja + 61 2 8884 1518 (Phone) + 61 2 8884 2000 (FAX) Jasjit.baveja@resmed.com.au
Official Contact	Larissa D'Andrea Director, Government & Regulatory Affairs ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123 +1 858 836 6837 (Phone) +1 858 836 5519 (Fax) Larissa.D'Andrea@resmed.com
Product codes	73 BZD
Class	II
Classification Reference	21 CFR 868.5905, Product Code 73 BZD
Common/Usual Name	Non continuous ventilator (IPPB)
Proprietary Name	AirCurve 10 ASV
Predicate device(s)	S9 Greenhills (K140279)

Reason for submission

This 510(k) is being submitted as a labelling change for the addition of the following contraindication:

ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF $\leq$ 45%) and moderate to severe predominant central sleep apnea.

This contraindication is supported by SERVE-HF, which was a randomized, parallel, event-driven, international multi-center study in 1325 patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF≤45%) and moderate to severe predominant central sleep apnea. The study investigated the effects of adding ASV to guideline-based medical management on survival and cardiovascular outcomes. The addition of ASV did not improve outcomes and showed an increased risk of cardiovascular mortality despite effective control of central sleep apnea.

Indication for Use

The AirCurve 10 ASV device is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate devices.

- Same intended use
- Same operating principle
- Similar technologies
- Same manufacturing process

ResMed has determined that the new device has not altered the safety and effectiveness of CPAP/Bilevel treatment for patients with Obstructive Sleep Apnoea (OSA), central and/or mixed apneas, or periodic breathing who weigh more than 66 lb (>30 kg).

The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use- Document Issued on: December 12, 2012
- FDA Draft Guidance for Industry and FDA Staff - Radio Frequency Wireless Technology in Medical Devices - Document Issued on: August 13, 2013
- Reviewer Guidance for Premarket Notification Submissions, ARDB, CDRH, FDA, November 1993.

As this was a labelling change only, no further clinical or non-clinical testing was required to show substantial equivalence to the predicate device S9 Greenhills (K140279).

The new device is as safe and effective as the predicate device.

Device Description

The AirCurve 10 ASV is identica to the predicate device, S9 Greenhills (K140279), using a blower based positive pressure system with an integrated heated humidifier and heater controller. The device platform is identical to the S9 Greenhills (K140279) and contains a Micro-processor controlled blower system that generates controlled positive airway pressure between 3-25 cmH_2O. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier.

The AirCurve 10 ASV is a flow generator device designed to provide adaptive servo-ventilation therapy (ASV mode) or (ASVAuto mode) to stabilize a patient's ventilation during sleep. The device continually measures the patient's instantaneous ventilation, and calculates a target ventilation based on to the patient's recent average minute ventilation. It then adjusts the degree of pressure support to servo-control the patient's ventilation to at least equal the target ventilation. The same is true for ASVAuto mode except the EPAP is adjusted to address any obstructive apneas detected.

Therapy modes contained in the AirCurve 10 ASV are CPAP, ASV, and ASVAuto. They are:

- CPAP mode – the device delivers a continuous positive airway pressure throughout the entire therapy session;
- ASV mode – the device automatically adjusts pressure support in response to the patient's recent average minute ventilation; and
- ASVAuto mode – the device automatically adjusts pressure support in response to the patient's recent average minute ventilation and EPAP level for OSA events.

The functional characteristics of the AirCurve 10 ASV system includes all the clinician and user friendly features of the predicate device which have been verified during usability studies in accordance with IEC 62366 Medical devices - Application of usability engineering to medical devices.

The functional characteristics of the system include all the clinician and user friendly features of the predicate device S9 Greenhills (K140279).

Characteristic	S9 Greenhills (K140279)	New Device (AirCurve 10 ASV)	Comments
Indication for use	The S9 Greenhills is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.	The AirCurve 10 ASV device is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.	Equivalent *Marketed name change only* *Only labeling change to include contraindication*
Location of use	Hospital/Home	Hospital/Home	Equivalent

Characteristic	S9 Greenhills (K140279)	New Device (AirCurve 10 ASV)	Comments
Pressure Range and Treatment Modes			
	4-20 cm H_2O (CPAP) 3-25 cm H_2O (ASV) 3-25 cm H_2O (ASVAuto)	4-20 cm H_2O (CPAP) 3-25 cm H_2O (ASV) 3-25 cm H_2O (ASVAuto)	Equivalent:
RAMP Settings	➢ User selected as "Off" to 45 minutes in 5 minute increments ➢ Max Ramp time set at clinician's discretion	➢ User selected as "Off" to 45 minutes in 5 minute increments ➢ Max Ramp time set at clinician's discretion	Equivalent
System Components	➢ Flow generator ➢ Humidifier ➢ Mask, air tubing and heated tubing	➢ Flow generator ➢ Humidifier ➢ Mask, air tubing and heated tubing	Equivalent
Power supply	100-240V, 50-60Hz	100-240V, 50-60Hz	Equivalent
Flow generator weight	2.5lb	2.5lb	Equivalent
Dimensions H x W x D (inches)	Flow generator unit: 4.5 x 9.6 x 6.0	Flow generator unit: 4.5 x 9.6 x 6.0	Equivalent
Supplemental oxygen	Labeled for use with supplemental oxygen	Labeled for use with supplemental oxygen	Equivalent

Conclusion

The AirCurve 10 ASV is substantially equivalent to the predicate device, S9 Greenhills (K140279).