



September 25, 2026

Respironics, Inc.
Viralyne Lipps
Principal Regulatory Affairs Specialist
1001 Murry Ridge Ln.
Murrysville, Pennsylvania 15668

Re: K261262
Trade/Device Name: Altis Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: August 28, 2026
Received: August 28, 2026

Dear Viralyne Lipps:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding

When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Binoy J.
Mathews -S**

Digitally signed by
Binoy J. Mathews -S
Date: 2026.09.25
12:02:32 -04'00'

For

James Lee, PhD
Division Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261262

?

Please provide the device trade name(s).

?

Altis Full Face Mask

Please provide your Indications for Use below.

?

The Altis Full Face Mask is intended to provide an interface for the application of non-invasive positive airway pressure (PAP) therapy. The mask is intended for single-patient reuse in the home environment and healthcare facilities and/or hospital environments. The mask is to be used by adult patients aged 22 years and older weighing more than 66lb (30kg) for whom non-invasive PAP therapy has been prescribed. The device is not intended for critical care patients.

Please select the types of uses (select one or both, as applicable).

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

?

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
☐ Infants (29 days old to < 2 years old)
☐ Children (2 years old to < 12 years old)
☐ Adolescents (12 years old to < 22 years old)
☒ Adults (22 years old and greater)

?

510(k) Summary**[As required by 21 CFR 807.92(c)]****Date Prepared:** September 24, 2026**I. Submitter****Company Name/Owner:** Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668, USA**Official Contact:** Viralyne Lipps
Principal Regulatory Affairs Specialist**II. Device****Device Trade Name:** Altis Full Face Mask
Device Common Name: Full Face Mask
Regulation Number: 21 CFR 868.5905
Classification Name: Noncontinuous ventilator (IPPB)
Product Code: BZD
Device Classification: Class II**III. Predicate Device****Predicate Device:** Resmed AirFit F20 Mask System; AirFit F20 NM Mask System (K242547)
Regulation Number: 21 CFR 868.5905
Classification Name: Noncontinuous ventilator (IPPB)
Product Code: BZD

This predicate has not been the subject of a design-related recall.

IV. Device Description

The Altis Full Face Mask is an over-the-nose, full-face mask with the hose connection in the front. The mask covers both the nose and mouth, ensuring pressurized air is delivered directly into the patient's airways with the use of a positive airway pressure (PAP) therapy device; it is intended for single-patient reuse in the home and healthcare facilities and/or hospital environments.

The mask consists of five main parts: a cushion (polycarbonate faceplate and bond ring with silicone seal), frame, exhalation elbow, headgear, and headgear clips. The elbow connects to standard ISO 5356-1 22 mm conical hoses.

V. Indications For Use

The Altis Full Face Mask is intended to provide an interface for the application of non-invasive positive airway pressure (PAP) therapy. The mask is intended for single-patient reuse in the home environment and healthcare facilities and/or hospital environments. The mask is to be used by adult patients aged 22 years and older weighing more than 66 lb (30 kg) for whom non-invasive PAP therapy has been prescribed. The device is not intended for critical care patients.

VI. Comparison with Predicate Device

Design/Technological Characteristic	Subject Device Altis Full Face Mask	Predicate Device AirFit F20 and Air Fit NM Mask Systems (K242547)	Comments
Product Code	BZD	BZD	Identical
Regulation Number	21 CFR 868.5905	12 CFR 868.5905	Identical
Classification Name	Non-continuous ventilator	Non-continuous ventilator	Identical
Regulatory Class	Class II	Class II	Identical
Classification Panel	Anesthesiology	Anesthesiology	Identical
Indications for Use / Intended Use	The Altis Full Face Mask is intended to provide an interface for the application of non-invasive positive airway pressure (PAP) therapy. The mask is intended for single-patient reuse in the home environment and healthcare facilities and/or hospital environments. The mask is to be used by adult patients aged 22 years and older weighing more than 66 lb (30 kg) for whom non-invasive PAP therapy has been prescribed. The device is not intended for critical care patients.	The AirFit F20 masks have two product variants: - The AirFit F20 variants are intended for single-patient reuse in the home environment - The AirFit F20 SLM (Sleep Lab Masks) variants are intended for multi-patient reuse in the hospital/institutional environment. These masks are intended for patients weighing more than 66lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Masks are the only variants that are validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients	Equivalent
Availability	Prescription use only	Prescription use only	Identical
Patient Population	Adult patients weighing more than 66 lb (30 kg)	Patients weighing more than 66 lb (30 kg)	Equivalent
Anatomical Sites	Nose and mouth	Nose and mouth	Identical
Operating Environment	Home or healthcare facilities and/or hospitals	Home or health institution	Equivalent
Operating and Storage Temperature Range	Operating: 5 °C to 40 °C Storage: -20 °C to +60 °C	Operating: 5 °C to 40 °C Storage: -20 °C to +60 °C	Identical
Patient Circuit Connection	ISO 5356-1 (22 mm)	ISO 5356-1 (22 mm)	Identical
Sizes	Cushion available in four sizes Headgear available in two sizes Frame available in one size	Cushion available in three sizes Headgear available in three sizes Frame available in one size	Equivalent
Exhalation Vent	Multi-hole vent array	Multi-hole vent	Equivalent
Sterile State as Provided	Non-sterile	Non-sterile	Identical

Design/Technological Characteristic	Subject Device Altis Full Face Mask	Predicate Device AirFit F20 and Air Fit NM Mask Systems (K242547)	Comments																				
Pressure Range	4 to 40 cm H ₂ O	3 to 40 cm H ₂ O	Equivalent																				
Mask Exhaust Flow (nominal)	<table><tr><th>Pressure (cmH₂O)</th><th>SLPM</th></tr><tr><td>4</td><td>16</td></tr><tr><td>13</td><td>32</td></tr><tr><td>22</td><td>44</td></tr><tr><td>31</td><td>55</td></tr><tr><td>40</td><td>64</td></tr></table>	Pressure (cmH ₂ O)	SLPM	4	16	13	32	22	44	31	55	40	64	<table><tr><th>Pressure (cmH₂O)</th><th>SLPM</th></tr><tr><td>3</td><td>19</td></tr><tr><td>20</td><td>54</td></tr><tr><td>40</td><td>82</td></tr></table>	Pressure (cmH ₂ O)	SLPM	3	19	20	54	40	82	Equivalent Disclosed per ISO 17510:2015 Annex B
Pressure (cmH ₂ O)	SLPM																						
4	16																						
13	32																						
22	44																						
31	55																						
40	64																						
Pressure (cmH ₂ O)	SLPM																						
3	19																						
20	54																						
40	82																						
Resistance to Flow (pressure drop)	<table><tr><th>@50l/min</th><th>@100l/min</th></tr><tr><td>0.2 cmH₂O</td><td>0.9 cmH₂O</td></tr></table>	@50l/min	@100l/min	0.2 cmH ₂ O	0.9 cmH ₂ O	<table><tr><th>@50l/min</th><th>@100l/min</th></tr><tr><td>0.2 cmH₂O</td><td>0.6 cmH₂O</td></tr></table>	@50l/min	@100l/min	0.2 cmH ₂ O	0.6 cmH ₂ O	Equivalent Disclosed per ISO 17510:2015 Annex C												
@50l/min	@100l/min																						
0.2 cmH ₂ O	0.9 cmH ₂ O																						
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Anti-Asphyxia Valve Operation	<table><tr><th>Open to atmosphere</th><th>Closed to atmosphere</th></tr><tr><td>1.5 cmH₂O</td><td>1.8 cmH₂O</td></tr></table>	Open to atmosphere	Closed to atmosphere	1.5 cmH ₂ O	1.8 cmH ₂ O	<table><tr><th>Open to atmosphere</th><th>Closed to atmosphere</th></tr><tr><td>1.5 cmH₂O</td><td>2.0 cmH₂O</td></tr></table>	Open to atmosphere	Closed to atmosphere	1.5 cmH ₂ O	2.0 cmH ₂ O	Equivalent (<min. rated pressure) ISO 17510:2015 Annex D												
Open to atmosphere	Closed to atmosphere																						
1.5 cmH ₂ O	1.8 cmH ₂ O																						
Open to atmosphere	Closed to atmosphere																						
1.5 cmH ₂ O	2.0 cmH ₂ O																						
Inspiratory and Expiratory Resistance	<table><tr><th>Resistance</th><th>@50SLPM</th></tr><tr><td>Inspiratory</td><td>1.6 cmH₂O</td></tr><tr><td>Expiratory</td><td>1.3 cmH₂O</td></tr></table>	Resistance	@50SLPM	Inspiratory	1.6 cmH ₂ O	Expiratory	1.3 cmH ₂ O	<table><tr><th>Resistance</th><th>@50SLPM</th></tr><tr><td>Inspiratory</td><td>0.60 cmH₂O</td></tr><tr><td>Expiratory</td><td>0.80 cmH₂O</td></tr></table>	Resistance	@50SLPM	Inspiratory	0.60 cmH ₂ O	Expiratory	0.80 cmH ₂ O	Equivalent (<10 cmH ₂ O) ISO 17510:2015 Annex E								
Resistance	@50SLPM																						
Inspiratory	1.6 cmH ₂ O																						
Expiratory	1.3 cmH ₂ O																						
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Inspiratory	0.60 cmH ₂ O																						
Expiratory	0.80 cmH ₂ O																						
CO ₂ Rebreathing (normal)	<table><tr><th>Pressure (cmH₂O)</th><th>Relative CO₂ increase</th></tr><tr><td>4 (min.)</td><td>12.4%</td></tr><tr><td>5</td><td>10.9%</td></tr><tr><td>10</td><td>7.0%</td></tr></table>	Pressure (cmH ₂ O)	Relative CO ₂ increase	4 (min.)	12.4%	5	10.9%	10	7.0%	<table><tr><th>Pressure (cmH₂O)</th><th>Relative CO₂ increase</th></tr><tr><td>3 (min.)</td><td>11.7%</td></tr><tr><td>5</td><td>7.3%</td></tr><tr><td>10</td><td>2.9%</td></tr></table>	Pressure (cmH ₂ O)	Relative CO ₂ increase	3 (min.)	11.7%	5	7.3%	10	2.9%	Equivalent (<20%) ISO 17510:2015 Annex F				
Pressure (cmH ₂ O)	Relative CO ₂ increase																						
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3 (min.)	11.7%																						
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CO ₂ Rebreathing (single fault)	<table><tr><th>Fault</th><th>Relative CO₂ increase</th></tr><tr><td>Case 1</td><td>27.8%</td></tr><tr><td>Case 2</td><td>26.6%</td></tr></table>	Fault	Relative CO ₂ increase	Case 1	27.8%	Case 2	26.6%	<table><tr><th>Fault</th><th>Relative CO₂ increase</th></tr><tr><td>Case 1</td><td>40.5%</td></tr><tr><td>Case 2</td><td>52.7%</td></tr></table>	Fault	Relative CO ₂ increase	Case 1	40.5%	Case 2	52.7%	Equivalent (<60%) ISO 17510:2015 Annex F								
Fault	Relative CO ₂ increase																						
Case 1	27.8%																						
Case 2	26.6%																						
Fault	Relative CO ₂ increase																						
Case 1	40.5%																						
Case 2	52.7%																						
Sound	Power level: 25 dBA Pressure level: 18 dBA	Power level: 30 dBA Pressure level: 23 dBA	Equivalent Disclosed per ISO 17510:2015 Annex G																				
Dead Space	≤ 248 mL	≤ 240 mL	Equivalent Disclosed characterization																				
Device Design	• Elbow • Frame • Cushion • Headgear	• Elbow • Frame • Cushion • Headgear	Identical																				
Construction Materials	Polycarbonate, silicone, polypropylene, woven/ laminate fabrics, magnets	Polymeric materials, Textile and magnets	Equivalent																				

Design/Technological Characteristic		Subject Device Altis Full Face Mask	Predicate Device AirFit F20 and Air Fit NM Mask Systems (K242547)	Comments
Faceplate / Cushion Type		Covers nose and mouth	Covers nose and mouth	Identical
Exhalation Device Design		Exhalation Elbow	Exhalation Elbow	Equivalent
Headgear Type		Adjustable headgear straps	Adjustable headgear straps	Equivalent
Validated Home Cleaning		Mild liquid detergent in warm water	Mild liquid detergent in warm water	Equivalent
Magnetic Clips	Number of Magnets	4	4	Equivalent
	Strength on the surface	<400 mT	<400 mT	Disclosed characterization
	Distance where strength <0.5mT	76mm	50 mm	

VII. Performance Data

Non-Clinical Tests

The Altis Full Face Mask subject device was designed in accordance with ISO 17510:2015, *Medical devices – Sleep apnoea breathing therapy – Masks and application accessories* and performance testing has demonstrated that the device meets the industry standard performance requirements. The following non-clinical bench performance tests were conducted:

- Exhaust flow (ISO 17510:2015 Annex B)
- Resistance to flow (ISO 17510:2015 Annex C)
- Anti-Asphyxia valve operating pressures (ISO 17510:2015 Annex D)
- Breathing resistance (ISO 17510:2015 Annex E)
- CO₂ rebreathing (ISO 17510:2015 Annex F)
- Vibration and noise (ISO 17510:2015 Annex G)
- Mask connectors (ISO 17510: 2015 Clause 5.1)

Other bench tests to verify product specifications were also completed:

- Minimum/maximum pressure performance testing
- Dead space volume determination
- Magnetic flux density determination for magnetic components
- Simulated transport and storage of packaging (ISTA 3A)
- Intentional mask leak and patient pressure drop
- Home cleaning validation

The biocompatibility of the Altis Full Face Mask was evaluated in accordance with ISO 10993-1:2018 – *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, ISO 18562-1:2024 – *Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process*, and the FDA guidance document *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, Issued September 8, 2023.

Validation of single-patient re-use reprocessing claims was evaluated in accordance with ISO 17664-1:2021 – *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices*, ANSI AAMI ST98:2022 – *Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices*, AAMI TIR12:2020 – *Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers*, and the FDA guidance document, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, updated June 9, 2017, included a combination of cleaning efficacy, residual toxicity, and performance testing.

The Altis Full Face Mask has been tested in accordance with the applicable requirements of the following standards:

- ISO 5356-1:2015 – Anaesthetic respiratory equipment – Conical connectors – Part 1: Cones and sockets
- ISO 10993-1:2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 – Biological evaluation of medical devices – Part 10: Tests for skin sensitization
- ISO 10993-12:2021 – Biological evaluation of medical devices – Part 12: Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 10993-17:2023 – Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents
- ISO 10993-18:2020 + A1:2022 – Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process – Amendment 1: Determination of the uncertainty factor
- ISO 10993-23:2021 – Biological evaluation of medical devices – Part 23: Tests for irritation
- ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
- ISO 17510:2015 – Medical devices – Sleep apnoea breathing therapy – Masks and application accessories
- ISO 17664-1:2021 – Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices
- ISO 18562-1:2024 – Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2024 – Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2024 – Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds
- ISO 18562-4:2024 – Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate
- ISO 20417:2021 – Medical devices – Information to be supplied by the manufacturer
- IEC 62366-1:2015+AMD1:2020 – Medical devices – Part 1: Application of usability engineering to medical devices
- ASTM F2503-23 – Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment

- ISTA 3A:2018 – Packaged Products for Parcel Delivery System Shipment 70kg (150lb. or less)
- ANSI AAMI ST98:2022 – Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
- AAMI TIR12:2020 – Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

VIII. Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of the Altis Full Face Mask. All risks have been sufficiently mitigated and product functionality has been adequately assessed by non-clinical tests.

IX. Conclusion

The Altis Full Face Mask is substantially equivalent to the predicate device, the Resmed AirFit F20 and Air Fit NM Mask Systems (K242547) based on its intended use and technological characteristics. The results of the verification testing also confirm compliance with FDA recognized consensus standards that were also evaluated by the predicate device. These evaluations support the conclusion that the subject device does not raise new questions of safety or efficacy.