December 30, 2024

Respironics, Inc.
Gary LeMere
Principal Regulatory Affairs Specialist
1001 Murry Ridge Ln
Murrysville, Pennsylvania 15668

Re: K243394
Trade/Device Name: AF531 Oro-Nasal SE Face Mask
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: October 31, 2024
Received: October 31, 2024

Dear Gary Lemere:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243394

Device Name

AF531 Oro-Nasal SE Face Mask

Indications for Use *(Describe)*

Medium and Large Size:
The AF531 Oro-Nasal SE Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency, or obstructive sleep apnea. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients (>30 kg) who are appropriate candidates for noninvasive ventilation.

Small Size:
The AF531 Oro-Nasal SE Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency, or obstructive sleep apnea. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients 7 years or older (>20 kg) who are appropriate candidates for noninvasive ventilation.

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 – K243394

Date Prepared	December 27, 2024
Company Name/ Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 733-0200
Official Contact	Gary LeMere Principal Regulatory Affairs Specialist
Proprietary Name(s)	AF531 Oro-Nasal SE Face Mask
Common/Usual Name	Oro-Nasal Face Mask
Classification	Class II
Product Code	CBK – ventilator, continuous, facility use
Regulation Name	Continuous ventilator
Regulation Number	21 CFR 868.5895
Review Panel	Anesthesiology
Primary Predicate Device 510(k) Product Code	AF541 SE Full Face Mask K150638 CBK
Secondary Predicate Device 510(k) Product Code	AF531 SE Full Face Mask K101129 CBK

Device Description

The AF531 Oro-Nasal SE Face Mask is designed for single-patient use in the hospital or institutional environment. AF531 Oro-Nasal SE Face Mask covers the nose and mouth while avoiding the eye region. The mask is available in three (3) sizes: Small, Medium, and Large.

The headgear options for the AF531 Oro-Nasal Masks include the four-point headgear and a CapStrap headgear.

The AF531 Oro-Nasal SE Face Mask requires use of a separate exhalation device. The mask utilizes a click-style elbow that secures to the mask hub yet can be removed by pressing the release tabs.

Indications for Use

AF531 Oro-Nasal SE Face Mask

Medium and Large Size: The AF531 Oro-Nasal SE Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency, or obstructive sleep apnea. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients (>30 kg) who are appropriate candidates for noninvasive ventilation.

Small Size: The AF531 Oro-Nasal SE Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency, or obstructive sleep apnea. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients 7 years or older (>20 kg) who are appropriate candidates for noninvasive ventilation.

Comparison Table 1: AF531 Oro-Nasal SE Face Mask

Design Parameter or Feature	**Subject Device:** AF531 Oro-Nasal SE Face Mask	**Primary Predicate** AF541 SE Full Face Mask K150638 (September 18, 2015)	**Secondary Predicate:** AF531 SE Full Face Mask K101129 (September 16, 2010)	**Comments**
		Intended Use		
Classification Product Code	CBK	CBK	CBK	Identical
Regulation Number	21 CFR§ 868.5895	21 CFR§ 868.5895	21 CFR§ 868.5895	Identical
Classification	II	II	II	Identical
Indications for Use	Medium and Large: The AF531 Oro-Nasal SE Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which	The AF541 SE Full Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are	The AF531 SE Full Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and	Equivalent

Design Parameter or Feature	**Subject Device:** AF531 Oro-Nasal SE Face Mask with click-style elbow	**Primary Predicate** AF541 SE Full Face Mask K150638 (September 18, 2015)	**Secondary Predicate:** AF531 SE Full Face Mask K101129 (September 16, 2010)	**Comments**
	are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients (>30 kg) who are appropriate candidates for noninvasive ventilation. <u>Small</u>: The AF531 Oro-Nasal SE Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients 7 years or older (>20 kg) who are appropriate candidates for noninvasive ventilation.	intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea. The mask is for single use in the hospital/ institutional environment only. The mask is to be used on patients (>40lbs/20kg) who are appropriate candidates for noninvasive ventilation.	which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency, or obstructive sleep apnea. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients 7 years or older (>40lbs/20kg) who are appropriate candidates for noninvasive ventilation	
Patient Population	Small Size: Patients >7 years (>20kg) Medium/Large Size: >30kg	All sizes: Patients >40lbs/20kg	Small Size: Patients >7 years (>40lbs/20kg)	Equivalent
Functional Indication	Interface for application of noninvasive ventilation	Interface for application of noninvasive ventilation	Interface for application of noninvasive ventilation	Identical
Environment of Use	Hospital/ Institutional Environment	Hospital/ Institutional Environment	Hospital/ Institutional Environment	Identical
Reprocessing Claims	Single use	Single use	Single use	Identical
Anatomical Sites	Nose and mouth	Nose and mouth	Nose and mouth	Identical

Design Parameter or Feature	**Subject Device:** AF531 Oro-Nasal SE Face Mask with click-style elbow	**Primary Predicate** AF541 SE Full Face Mask K150638 (September 18, 2015)	**Secondary Predicate:** AF531 SE Full Face Mask K101129 (September 16, 2010)	**Comments**
Technological Characteristics				
Sterile State as Provided	Non-Sterile	Non-Sterile	Non-Sterile	Identical
Useful Life	≤ 7 days	Not Defined	Not Defined	Equivalent
Device Design	• Polycarbonate faceplate • Silicone cushion • Click-Style Elbows • SE option without entrainment valve • Elbow retention hub to retain click-style elbow • Headgear • Accessory Port Cap	• Nylon Faceplate • Silicone cushion • Click-Style Elbows • SE option without entrainment valve • No elbow retention hub integral to AF541 design; elbows attach via faceplate • Headgear • Accessory Port Cap	• Polycarbonate faceplate • Silicone cushion • Press-fit Elbows • SE option without entrainment valve • Elbow retention hub to retain press-fit elbow • Headgear • Pick-off Port Cap	Equivalent
Faceplate/ Cushion Type	Covers nose and mouth	Covers nose and mouth	Covers nose and mouth	Identical
Exhalation Device Design	Separate exhalation device required	Separate exhalation device required	Separate exhalation device required	Identical
Headgear Type	CapStrap or four-point headgear	CapStrap or four-point headgear	CapStrap or four-point headgear	Identical
Patient Circuit Connection	22mm click-style elbow with 22mm connector	22mm click-style elbow with 22mm connector	22mm press-fit elbow with 22mm connector	Equivalent
Mask Sizes	Small, Medium, and Large	Small, Medium, Large, and Extra-Large	Small	Equivalent
Materials – Elbows	SE Click-Style Elbow: Polypropylene (Blue) Accessory Port Cap: Silicone	SE Click-Style Elbow: Polypropylene (Blue) Accessory Port Cap: Silicone	SE Press-Fit Elbow: Polycarbonate (Blue) Pick-off Port Cap: Silicone	Identical to Primary predicate
Materials – Mask and Headgear Component	**Mask Materials**: Faceplate: Polycarbonate/polysiloxane Cushion: Polysiloxane Click-Style Elbow Hub: Polycarbonate Split Washer: Polycarbonate Forehead Arm**:** Polycarbonate/ polysiloxane Support Retaining Clip: Polycarbonate Forehead Bracket: Polycarbonate/ polysiloxane Disposable Foam Forehead Spacer: Polyurethane foam	**Mask Materials**: Faceplate: Nylon Over the nose / under the nose Cushion: Silicone Over the Nose / under the nose Hub: Nylon Headgear Materials: 4 Point Crown Headgear Materials: Forehead Pad Bracket: Nylon Forehead Adjuster Ball Post: Nylon Forehead Adjuster Button: Nylon Disposable Foam Forehead Spacer: Polyurethane	**Mask Materials**: Faceplate: Polycarbonate/ polysiloxane Cushion: Polysiloxane Press-Fit Elbow Hub: Polycarbonate Split Washer: Polycarbonate Forehead Arm: Polycarbonate/ polysiloxane Support Retaining Clip: Polycarbonate Forehead Bracket: Polycarbonate/ polysiloxane Disposable Foam Forehead Spacer: Polyurethane foam	Equivalent

Design Parameter or Feature	**Subject Device:** AF531 Oro-Nasal SE Face Mask with click-style elbow	**Primary Predicate** AF541 SE Full Face Mask K150638 (September 18, 2015)	**Secondary Predicate:** AF531 SE Full Face Mask K101129 (September 16, 2010)	**Comments**
		Headgear Clip: Polypropylene, Tension Clip: Polyoxymethylene Velcro Hook: Nylon Headgear Material: Nylon Polyester Polyurethane, Nylon		
	CapStrap Materials: CapStrap Halo: Nylon CapStrap Soft Goods: Nylon, Polyester/ Polyurethane, Polyester/Lycra Knit Elastic CapStrap Clip: Acetal copolymer	**CapStrap Headgear**: Cap: Nylon Fabric, Foam, Pad Bracket: Nylon Adhesive: Loctite Headgear Clip: Polypropylene Velcro Hook: Nylon	**CapStrap Materials**: CapStrap Halo: Nylon CapStrap Soft Goods: Nylon, Polyester/ Polyurethane, Polyester/Lycra Knit Elastic CapStrap Clip: Acetal copolymer	
	Headgear Materials: Headgear Clip: Acetal copolymer Headgear Material: Nylon, Lycra, Polyester/ polyurethane, Polyoxymethylene	**Headgear Material**: Nylon Polyester Polyurethane	**Headgear Materials**: Headgear Clip: Acetal copolymer. Headgear Material: Nylon, Lycra Polyester/ polyurethane, Polyoxymethylene	
Performance Specifications				
Pressure Range	4 to 40cmH_2O	4 to 40cmH_2O	4 to 40cmH_2O	Identical
Total Mask Leak	Specification: ≤15 SLPM@4.0cmH_2O ≤25 SLPM@40.0cmH_2O	SE Specification, all sizes: ≤15 SLPM@4.0cmH_2O ≤25 SLPM@40.0cmH_2O	Specification: ≤15 SLPM@4.0cmH_2O ≤25 SLPM@40.0cmH_2O	Identical
Pressure Drop	Specifications: ≤ 1.0cmH_2O@50SLPM ≤ 4.0cmH_2O@100SLPM	Specifications: ≤ 1.0cmH_2O@50SLPM ≤ 4.0cmH_2O@100SLPM	Specifications: ≤ 1.0cmH_2O@50SLPM ≤ 4.0cmH_2O@100SLPM	Identical
Sound Power and Pressure Level	Test results at 10cmH_2O: Power Level:18.2dBA@1m Pressure Level:10.9dBA@1m	Test results: Power Level:16.5dBA Pressure Level:9.4dBA	Not provided in original submission	Equivalent
Deadspace Volume (mL)	Specification: S: <350mL M: <525mL L: <650mL	Specification: S: <700mL M: <700mL L: <700mL	Specification: S: <350mL	Equivalent
NIVO Nebulizer Compatibility	Compatible with NIVO Nebulizer	Compatible with NIVO Nebulizer	Compatible with the Aerogen SE elbow and NIVO Nebulizer	Equivalent

Discussion of Similarities and Differences

The subject device AF531 Oro-Nasal SE Face Mask has the following similarities and differences in comparison to the predicate devices:

Similarities:

- Intended use
- Product Code
- Operating Principle
- Similar Design
- Similar Materials
- Compatible with NIVO Nebulizer

Differences:

- The subject device has the click fit elbow design that was not present on the secondary predicate device
- Minor design / material changes to hub to accommodate the click style elbow

Discussion on Differences:

The difference between the subject device and the secondary predicate is the incorporation of the click-style elbow with hub that replaces the press fit elbow. This characteristic does not differ from the primary predicate. The change to incorporate the click style elbow does not represent a technologically different characteristic.

Non-Clinical Data Submitted

Non-clinical verification testing completed for the new device demonstrated that the AF531 Oro-Nasal SE Face Mask with click-style elbow met all intended performance requirements. These include:

- Total Mask Leak
- Pressure Drop Closed to Atmosphere
- Sound Testing and Pressure Level
- Physical Dead Space

AF531 Oro-Nasal SE Face Mask with the click-style elbow was designed and tested in accordance with the applicable relevant consensus standards including:

ISO 17510:2015	Medical devices – Sleep apnoea breathing therapy – Masks and application accessories
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
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 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)
ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate
ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
ISO 14971-1:2019	Medical devices – Application of risk management to medical devices
ISO 5356-1:2004	Anaesthetic and respiratory equipment – Conical connectors Part 1: Cones and sockets

Substantial Equivalence Conclusion

The subject device, AF531 Oro-Nasal SE Face Mask with click-style elbow, is substantially equivalent to the predicate devices, AF541 SE Full Face Mask (K150638) and AF531 SE Full Face Mask (K101129).