



January 15, 2026

Sleepnet Corporation
% Todd Courtney
Vice President, Anesthesia, Respiratory, Sleep, and ENT Regulatory Affairs
Mcra, LLC
803 7th Street, NW
3rd Floor
Washington, District of Columbia 20001

Re: K251847

Trade/Device Name: Sleepnet Arie Full Face Vented Mask; Sleepnet Arie Nasal Vented Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 11, 2025
Received: December 15, 2025

Dear Todd Courtney:

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,

**Binoy J.
Mathews -S** Digitally signed by
Binoy J. Mathews -S
Date: 2026.01.15
11:23:52 -05'00'

For

Rachana Visaria
Assistant 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

510(k) Number (if known)
K251847

Device Name

Sleepnet Arie Full Face Vented Mask;
Sleepnet Arie Nasal Vented Mask

Indications for Use (Describe)

The Sleepnet Arie Full Face Vented Mask is intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 4 cm H₂O. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single-patient multi-use in the home, hospital, or institutional environment.

The Sleepnet Arie Nasal Vented Mask is intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 4 cm H₂O. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single-patient multi-use in the home, hospital, or 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Device Trade Name: Arie Full Face Vented Mask and Arie Nasal Vented Mask

Manufacturer: Sleepnet Corporation
5 Merrill Industrial Drive
Hampton, NH 03842

Contact: Todd Courtney
Vice President, Anesthesia, Respiratory, Sleep, and ENT
Regulatory Affairs
MCRA, LLC
Office: (202) 552-5800

Prepared by: MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: January 15, 2026

Classifications: 21 CFR 868.5905; Noncontinuous ventilator (IPPB)

Class: II

Product Codes: BZD

510(k) Number: K251847

Primary Predicate: AirFit F20 Full Face Mask, K153563 (for Arie Full Face Vented Mask)
AirFit N20 Nasal Mask, K171212 (for Arie Nasal Vented Mask)

Reference Device: F&P Evora Full Face Mask, K212371 (for Arie Full Face Vented Mask only)

Indications For Use:

Arie Full Face Vented Mask

The Sleepnet Arie Full Face Vented Mask is intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 4 cm H₂O. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single-patient multi-use in the home, hospital, or institutional environment.

Arie Nasal Vented Mask

The Sleepnet Arie Nasal Vented Mask is intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 4 cm H₂O. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single-patient multi-use in the home, hospital, or institutional environment.

Device Description:

The Sleepnet Arie Full Face Vented and Nasal Mask are designed based on the human facial shape, and the operating characteristics during application. The Sleepnet mask utilizes a Liquid Silicone Rubber (LSR) cushion design. The device is composed of medical-grade injection molded thermoplastics & clear liquid silicone rubber. The device is used as the interface between a CPAP/BiPAP machine and the end user. The masks are held in place with adjustable headgear that straps the mask to the face.

The Arie Full Mask is accompanied by a vented frame/tubing assembly which includes the Arie Full Face Vented Mask Headgear connector, valve, swivel ball, tubing, swivel connector assembly (swivel connector and clear swivel), and the JustFit Full Face Headgear with clips.

Predicate Device:

Sleepnet submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Arie Full Face Vented and Nasal Vented Mask is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: AirFit F20 Full Face Mask, K153563 (for Arie Full Face Vented Mask)
 AirFit N20 Nasal Mask, K171212 (for Arie Nasal Vented Mask)

Reference Device: F&P Evora Full Face Mask, K212371 (for Arie Full Face Vented Mask only)

Performance Testing Summary:

The following tests have been performed on the Arie Full Face Vented and Nasal Vented Masks:

- CO₂ Rebreathing
- Exhaust Flow Test
- Pressure Drop Test
- Dead Space Measurement
- Anti-Asphyxia Valve Pressure Test
- Anti-Asphyxia Valve Breathing in Resistance Test
- Anti-Asphyxia Valve Life Test
- Sound Test

Tests were conducted according to recognized standards:

- ISO 17510: Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
- ISO 3744: Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane
- ISO 5356: Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets
- IEC 60068-2-31: Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens
- ISO 17664: Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
- ISO 10993-1: Biological evaluation of medical devices. Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
- ISO 10993-5: Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: Biological evaluation of medical devices. Part 10: Tests for skin sensitization
- ISO 10993-12: Biological evaluation of medical devices. Part 12: Sample preparation and reference materials
- ISO 10993-18:2020/Amd1:2022: Biological evaluation of medical devices. Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 10993-23: 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: Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 2: Tests for emissions of particulate matter
- ISO 18562-3: Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 3: Tests for emissions of volatile organic substances

Substantial Equivalence:

The Arie Full Face Vented and Nasal Vented Masks are substantially equivalent to AirFit F20 Full Face Mask (K153563) and AirFit N20 Nasal Mask (K171212) with respect to intended use, patient population, exhaust flow, AAV pressure, pressure drop, and therapy pressure range.

Table 1: Substantial Equivalence -Arie Full Face Vented Mask

	Subject Device	Primary Predicate	Reference Device	Comparison to Primary Predicate
Device Name	Arie Full Face Vented Vented Mask	Resmed AirFit F20 Full Face Mask	F&P Evora Full Face Mask	N/A
Company	Sleepnet Corporation	Resmed Ltd	Fisher & Paykel Healthcare Ltd	N/A
510(k) Number	K251847	K153563	K212371	N/A
Classification	21 CFR 868.5905	21 CFR 868.5905	21 CFR 868.5905	Identical
Product Code	BZD	BZD	BZD	Identical
Common/ Usual Name	CPAP/BiPAP Mask	Full Face Mask	Full Face Mask	Identical
Principle of Operation	Seal over the nose and mouth to allow delivery of pressurized air from a PAP device. Interface for CPAP device or Bi-level/Auto-PAP devices	Interface for CPAP device or Bi-level/Auto-PAP devices	Interface for CPAP device or Bi-level/Auto-PAP devices	Identical
Patient Use Type	Adult Subjects >30kg	Adult Subjects >30kg	Adult Subjects >30kg	Identical
Indications for Use	Arie Full Face Vented Mask is intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 4 cm H ₂ O. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single-patient multi-use in the home, hospital, or institutional environment.	The AirFit F20 is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system. The AirFit F20 is: <ul style="list-style-type: none"> to be used by patients weighing more than 66 lb (30 kg) for whom positive airway pressure therapy has been prescribed intended for single-patient reuse in the home environment and multi-patient reuse in the hospital/institutional environment. 	The F&P Evora Full Face mask is intended to be used by adults weighing ≥ 66lbs (30kgs) who have been diagnosed by a physician as requiring CPAP or Bi-Level therapy. The F&P Evora Full Face mask is intended for single patient use in the home and for multiple patient use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses	Comparable. The proposed devices's indications are a subset of the proposed predicates, as the subject device is not intended to be multi-patient use, which reduces the overall risk of the subject device compared to the predicate.
Environment	Home, hospital or institutional environment	Home, hospital or institutional environment	Home, hospital or institutional environment	Identical

	Subject Device	Primary Predicate	Reference Device	Comparison to Primary Predicate												
Operating and Storage Conditions	Operating Temperature: 5°C to 40°C Storage Temperature: -20°C to 60°C	Not Publicly Available	Operating Temperature: 5°C to 40°C Storage Temperature: -20°C to 50°C	Identical to reference												
Reuse	Single patient, multi-use	Single patient, Multi-Use Multiple patient use	Single patient, Multi-Use Multiple patient use	Comparable. The subject device is not intended to be used on multiple patients, only single patient, multi-use which reduces the overall risk of the subject device compared to the predicate.												
Useful Life	12 months	Not Publicly Available	24 months	N/A												
Anatomical site	Face (seals around the nose and mouth)	Face (seals around the nose and mouth)	Face (seals around the nose and mouth)	Identical												
Mask Size	Three sizes available – Small, Medium, Large	Offered in various sizes	Three sizes available – Extra Small, Small-Medium, Large	Similar												
Mask Weight	Small – 68 grams Medium – 75 grams Large – 85 grams	Not Publicly Available	Not Publicly Available	N/A												
Exhaust flow characteristics	<table border="1"> <thead> <tr> <th>Pressure (cm H₂O)</th> <th>Flow (lpm)</th> </tr> </thead> <tbody> <tr> <td>4</td> <td>28.5</td> </tr> <tr> <td>10</td> <td>39.1</td> </tr> <tr> <td>20</td> <td>54.9</td> </tr> <tr> <td>30</td> <td>67.2</td> </tr> <tr> <td>40</td> <td>81.2</td> </tr> </tbody> </table>	Pressure (cm H ₂ O)	Flow (lpm)	4	28.5	10	39.1	20	54.9	30	67.2	40	81.2	Not Publicly Available	Not Publicly Available	The exhaust flow plays a critical role in washing out the exhaled CO ₂ . The CO ₂ washout test was successfully completed on the Large size of the subject device, thus proving that the exhaust flow is acceptable.
Pressure (cm H ₂ O)	Flow (lpm)															
4	28.5															
10	39.1															
20	54.9															
30	67.2															
40	81.2															
Mask Dead Space	Small: 140 mL Medium: 225 mL Large: 240 mL	Not Publicly Available	XS: 165.2 cm ³ S-M: 162.6 cm ³ L: 164.1 cm ³	Comparable. The dead space also plays a critical role in washing												

	Subject Device	Primary Predicate	Reference Device	Comparison to Primary Predicate
				out the exhaled CO ₂ . The CO ₂ washout test was successfully completed on the Large size of the subject device, thus proving that the dead space is acceptable.
Sound Power Level	<ul style="list-style-type: none"> • A-weighted Sound Power Level: 32.1 dBA • A-weighted Sound Pressure Level at 1m distance: 24.1 dBA 	Not Publicly Available	<ul style="list-style-type: none"> • A-weighted Sound Power Level of the Mask: 28.2 dBA, with uncertainty 2.5 dBA • Sound Pressure Level of the Mask: 20.2 dBA, with uncertainty 2.5 dBA 	Similar
AAV pressure	<ul style="list-style-type: none"> • AAV opening pressure: 1.16 cm H₂O • AAV closing pressure: 1.82 cm H₂O 	Not Publicly Available	Not Publicly Available	ISO 17510 requires that the AAV opening pressure be less than the minimum rated therapy pressure. As seen, the opening pressure is less than 4 cm H ₂ O for the subject device.
Sterility	Provided Non-Sterile	Provided Non-Sterile	Provided Non-Sterile	Identical
Validated Cleaning (Single-Patient Use)	Mild soap and warm water.	Not Publicly Available	Not Publicly Available	Cleaning instructions are validated and include mild soap/detergent and warm water.
Validated Disinfection	N/A	Not Publicly Available	Thermal Disinfection: 90°C for 1 min	Different. The subject device is not intended to be used on multiple patients so disinfection is not required.

	Subject Device		Primary Predicate	Reference Device	Comparison to Primary Predicate
Therapy Pressure Range	4 to 40 cm H ₂ O.		Not Publicly Available	4 to 30 cmH ₂ O	Similar
Resistance to Flow (Pressure drop)	<ul style="list-style-type: none"> Pressure drop at 50 L/min: 1.05 cm H₂O Pressure drop at 100 L/min: 3.09 cm H₂O 		Not Publicly Available	<ul style="list-style-type: none"> Pressure drop at 50 L/min: 0.9 ± 0.3 cm H₂O Pressure drop at 100 L/min: 2.2 ± 0.3cm H₂O 	<p>Comparable. The pressure drop is slightly higher for the subject device than for the reference predicate. There are no acceptance criteria in ISO 17510 for pressure drop. The pressure drop values are typically disclosed in the IFU's as a reference for the clinicians so that the therapy pressure setting can be compensated accordingly.</p> <p>The F&P Evora has a more comparable pressure drop to the subject device and is included as a reference device.</p>
Materials	Polycarbonate, Liquid Silicone Rubber, Polypropylene, TPE		Not Publicly Available	Not Publicly Available	Biocompatibility was tested via FDA recognized standards
CO ₂ Rebreathing	Condition	ETCO₂: Percentage Relative Increase over Baseline	Not Publicly Available	Not Publicly Available	The subject device meets ISO 17510 acceptance criteria for CO ₂ rebreathing. Maximum allowable increase in ETCO ₂ in normal condition is 20% and in single fault condition is 60%.
	<u>Normal:</u> 4 cm H ₂ O 5 cm H ₂ O 10 cm H ₂ O <u>Single Fault:</u> SF1 – Open end SF2 - Occluded	16% 14% 12% 35% 36%			

Table 2: Substantial Equivalence -Arie Nasal Vented Mask

	Subject Device	Proposed Predicate	Comparison
Device Name	Arie nasal vented mask	AirFit N20 Nasal Mask	N/A
Company	Sleepnet Corporation	Resmed Ltd	N/A
510(k) Number	K251847	K171212	N/A
Classification	21 CFR 868.5905	21 CFR 868.5905	Identical.
Product Code	BZD	BZD	Identical.
Common/ Usual Name	CPAP/BiPAP Mask	Vented Nasal Mask	Similar
Principle of Operation	Seal over the nose to allow delivery of pressurized air from a PAP device. Interface for CPAP or Bi-level/Auto-PAP devices	Seal over the nose to allow delivery of pressurized air from a PAP device. Interface for CPAP or Bi-level/Auto-PAP devices	Identical.
Patient Use Type	Adult Subjects >30kg	Adult Subjects >30kg	Identical.
Indications for Use	Arie Nasal Vented Mask is intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 4 cm H ₂ O. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single-patient multi-use in the home, hospital, or institutional environment.	The AirFit N20 channels airflow non-invasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device. The AirFit N20 is: <ul style="list-style-type: none"> to be used by patients weighing more than 66 lb (30 kg) for whom positive airway pressure has been prescribed intended for single patient re-use in the home environment and multi-patient re-use in the hospital / institutional environment 	Comparable. The proposed devices' indications are a subset of the proposed predicates, as the subject device is not intended to be multi-patient use.
Environment	Home, hospital or institutional environment	Home, hospital or in stitutional environment	Identical.
Operating and Storage Conditions	Operating Temperature: 5°C to 40°C Storage Temperature: -20°C to 60°C	Not Publicly Available	Identical.

	Subject Device	Proposed Predicate	Comparison										
Reuse	Single patient, multi-use	<ul style="list-style-type: none"> Single patient, Multi-Use Multiple patient use 	Comparable. The subject device is not intended to be used on multiple patients, only single patient, multi-use.										
Useful Life	12 months	Not Publicly Available	N/A										
Anatomical site	Face (seals around the nose)	Face (seals around the nose)	Identical.										
Mask Size	Three size available – Small, Medium, Large	Offered in various sizes	Identical.										
Mask Weight	Small – 41 grams Medium – 44 grams Large – 46 grams	Not Publicly Available	N/A										
Exhaust flow characteristics	<table border="0"> <tr> <td><u>Pressure (cm H₂O)</u></td> <td><u>Flow (lpm)</u></td> </tr> <tr> <td>4</td> <td>23.0</td> </tr> <tr> <td>10</td> <td>35.9</td> </tr> <tr> <td>20</td> <td>50.5</td> </tr> <tr> <td>30</td> <td>63.8</td> </tr> </table>	<u>Pressure (cm H₂O)</u>	<u>Flow (lpm)</u>	4	23.0	10	35.9	20	50.5	30	63.8	Not Publicly Available	The exhaust flow plays a critical role in washing out the exhaled CO ₂ . The CO ₂ washout test was successfully completed on the Large size of the subject device, thus proving that the exhaust flow is acceptable.
<u>Pressure (cm H₂O)</u>	<u>Flow (lpm)</u>												
4	23.0												
10	35.9												
20	50.5												
30	63.8												
Mask Dead Space	Small: 60 mL Medium: 75 mL Large: 95 mL	Not Publicly Available	The dead space also plays a critical role in washing out the exhaled CO ₂ . The CO ₂ washout test was successfully completed on the Large size of the subject device, thus proving that the dead space is acceptable.										
Sound Power Level	A-weighted sound power level: 28.4 dBA. A-weighted sound pressure level at 1m distance: 20.4 dBA.	Not Publicly Available	Comparable. The sound power levels of the machines are within SIO 17510 limits										
Sterility	Provided Non-Sterile	Provided Non-Sterile	Identical.										
Validated Cleaning (Single-Patient Use)	Mild soap and warm water;	Not Publicly Available	Validated cleaning instructions include mild soap/detergent and warm water.										
Validated Disinfection	N/A	Not Publicly Available	The subject device is not intended to be used on multiple patients so disinfection is not required.										
Therapy Pressure Range	4 to 30 cm H ₂ O.	Not Publicly Available	Subject device performance has been evaluated per applicable ISO 17510 requirements across the stated pressure range.										

	Subject Device		Proposed Predicate	Comparison
Resistance to Flow (Pressure drop)	<ul style="list-style-type: none"> Pressure drop at 50 L/min: 0.43 cm H₂O Pressure drop at 100 L/min: 1.98 cm H₂O 		Not Publicly Available	There are no acceptance criteria in ISO 17510 for pressure drop. The pressure drop values are typically disclosed in the IFU's as a reference for the clinicians and RT's so that the therapy pressure setting can be compensated accordingly.
Materials	Polycarbonate, Liquid Silicone Rubber, Polypropylene, TPE		Not Publicly Available	Materials were validated via FDA recognized biocompatibility testing.
CO ₂ Rebreathing	Condition	ETCO₂: Percentage Relative Increase over Baseline	Not Publicly Available	The subject device meets ISO 17510 acceptance criteria was CO ₂ rebreathing. Maximum allowable increase in ETCO ₂ in normal condition is 20%. <u>Note</u> – As per ISO 17510, CO ₂ rebreathing testing in single fault condition is not required for a nasal mask.
	<u>Normal:</u> 4 cm H ₂ O 5 cm H ₂ O 10 cm H ₂ O	17% 11% 3%		

Conclusion:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.