May 19, 2025

ResMed Pty Ltd
℅ Jason Gorman
Senior Director, Regulatory Affairs
ResMed Corp
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K242547
Trade/Device Name: AirFit F20 Mask System; AirFit F20 NM Mask System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: April 17, 2025
Received: April 17, 2025

Dear Sheila Bruschi:

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,

Rachana Visaria -S

Rachana Visaria, PhD.
Assistant Director
DHT1C: Division of Anesthesia,
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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.

510(k) Number *(if known)*
K242547

Device Name
AirFit F20 Mask System;
AirFit F20 NM Mask System

Indications for Use *(Describe)*

AirFit F20 Mask System:
The AirFit F20 mask has two product variants:
• AirFit F20 mask is intended for single-patent reuse in the home environment.
• AirFit F20 SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.
Both 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 Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocesssed if reused between patients.

AirFit F20 NM Mask System:
The AirFit F20 Non Magnetic mask has two product variants:
• The AirFit F20 Non Magnetic variant is intended for single-patient reuse in the home environment.
• The AirFit F20 Non Magnetic SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.
This mask is for patients weighing more than 66 lb (30 kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.

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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1 510(k) Summary

[As required by 21 CFR 807.92(c)]

Date of Submission: 26 August 2024

Company Name/Owner:
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Device Trade Name: AirFit F20 Mask System, AirFit F20 NM Mask System

Device Common Name: Vented Full Face Mask

Classification and Classification Name: 21 CFR 868.5905, BZD (Class II)
Accessory to Noncontinuous Ventilator (IPPB)

Product Code: BZD

Predicate Device: AirFit F20 (K170924)

Device Description

The AirFit F20 and AirFit F20 NM Mask Systems are both full-face masks intended for use with Continuous Positive Airway Pressure (CPAP) and/or Bi-Level devices. CPAP & Bi-Level devices are used for the treatment of Obstructive Sleep Apnea (OSA) and/or ventilatory support. Both treatments deliver pressurized air from a flow generator to the patient. Such delivery of pressurized air relies on the Patient Interface; commonly known as the mask. Full face masks are a common type of Patient Interface (Mask) and are known to efficaciously support the delivery of pressurized air by providing a seal around the patient's nose and mouth.

The AirFit F20 mask system has two product variants:

- **AirFit F20 Mask** : This is the home use variant that is intended for single patient re-use.
- **AirFit F20 SLM** (sleep lab mask): This is the variant that is intended for multi-patient re-use and must be reprocessed if reused between patients using the disinfection guide.

AirFit F20 (K170924) had a "For Her" variant which was cleared with aesthetic colour pops, the AirFit F20 Mask and AirFit F20 SLM also have the same "For Her" variant.

The AirFit F20 NM mask system has two product variants:

- **AirFit F20 NM Mask**: This is the home use variant that is intended for single patient re-use.
- **AirFit F20 NM SLM** (sleep lab mask): This is the variant that is intended for multi-patient re-use and must be reprocessed if reused between patients using the disinfection guide.

The AirFit F20 and AirFit F20 NM Mask Systems share a common design architecture as the predicate AirFit F20 (K170924), except that the AirFit F20 NM Mask System has non-magnetic clips.

The AirFit F20 and AirFit F20 NM mask systems are made up of the following four main component assemblies: cushion, elbow, frame, and headgear. The cushion and headgear are available in various sizes to allow for adequate mask fit over the intended patient population.

The AirFit F20 and AirFit F20 NM mask systems are prescription devices supplied non-sterile.

Indications for Use:

AirFit F20 Mask System:

The AirFit F20 mask has two product variants:

- AirFit F20 mask is intended for single-patent reuse in the home environment.
- AirFit F20 SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.

Both 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 Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocesssed if reused between patients.

AirFit F20 NM Mask System:

The AirFit F20 Non Magnetic mask has two product variants:

- The AirFit F20 Non Magnetic variant is intended for single-patient reuse in the home environment.
- The AirFit F20 Non Magnetic SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.

This mask is for patients weighing more than 66 lb (30 kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.

Comparison Table

Design parameter or feature	**Predicate device:** AirFit F20, K170924	**Modified device:** AirFit F20 Mask System	**Modified device:** AirFit F20 NM Mask System	**Comments**
Indications for Use	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: • 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 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.	The AirFit F20 Non Magnetic mask has two product variants: • The AirFit F20 Non Magnetic variant is intended for single-patient reuse in the home environment • The AirFit F20 Non Magnetic SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment. This mask is intended for patients weighing more than 66 lb (30 kg) who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.	Equivalent
Intended Use	The mask is intended to provide an interface for CPAP or bi-level devices.	The mask is intended to provide an interface for CPAP or bi-level devices.		Identical
FDA Product Code	BZD	BZD		Identical
Patient population	Weighing more than 66 lb (30 kg)	Patients weighing more than 66lb (30kg)		Identical
Environment of Use	Home or health institution	Home or health institution.		Identical

Design parameter or feature	**Predicate device:** AirFit F20, K170924	**Modified device:** AirFit F20 Mask System	**Modified device:** AirFit F20 NM Mask System	**Comments**
Reprocessing claims	Single patient re-use or multi-patient re-use.	Single patient re-use or multi-patient re-use.		Identical
Sterility state as provided	Non-sterile	Non-sterile		Identical
Validated reprocessing methods	High-Level Thermal disinfection, Sterilization	High-Level Thermal disinfection, Sterilization		Identical
Vent type	Multi-hole vent	Multi-hole vent and diffuser vent		Equivalent
PAP tubing connection point	ISO 5356-1 (22mm)	ISO 5356-1 (22mm)		Identical
Construction material	Polymeric materials, Textile and magnets	Polymeric materials, Textile and magnets	Polymeric materials, Textile	Equivalent
Operating pressure range (cmH_2O)	3 - 40	3 – 40		Identical
Sizes	Cushion available in three sizes Headgear available in three sizes Frame available in one size	Cushion available in three sizes Headgear available in three sizes Frame available in one size		Identical
Mask exhaust flow (Nominal) ISO 17510:2015 Annex B	Pressure ($cm\ H_2O$) / Flow (L/min) 'Full Face' curve: 3 / 20.1 20 / 55.5 40 / 82.4	Pressure ($cm\ H_2O$) / Flow (L/min) 'Full Face' curve: 3 / 19 20 / 54 40 / 82	Pressure ($cm\ H_2O$) / Flow (L/min) 'Full Face' curve: 3 / 19 20 / 54 40 / 82	Equivalent

Design parameter or feature		**Predicate device:** AirFit F20, K170924		**Modified device:** AirFit F20 Mask System		**Modified device:** AirFit F20 NM Mask System		**Comments**
CO2 re-breathing performance (normal condition)	Pressure (cm H_2O)	**Relative CO_2 increase**		**Relative CO_2 increase**				Equivalent (<20%) ISO 17510:2015 Annex F
		Non-SLM	**SLM**	**Non-SLM**	**SLM**	**Non-SLM**	**SLM**	
	3	14.8%		11.7%	≤ 11.4%	11.7%	≤ 11.4%	
	5	7.5%		7.3%		7.3%		
	10	6.8%		2.9%		2.9%		
CO2 re-breathing performance (single fault condition)	Fault (ISO 17510:2015)	**Relative CO_2 increase**		**Relative CO_2 increase**				Equivalent (<60%) ISO 17510:2015 Annex F
		Non-SLM	**SLM**	**Non-SLM**	**SLM**	**Non-SLM**	**SLM**	
	Fault 1	32.3%		40.5 %	≤ 53.1%	40.5 %	≤ 53.1%	
	Fault 2	39.5%		52.7%		52.7%		
Resistance to flow (Pressure drop across mask in cmH_2O) ISO 17510:2015 Annex C		@50 L/min <0.8 cmH2O	@100 L/min <1.6 cmH2O	@50 L/min <0.8 cmH2O	@100 L/min <1.6 cmH2O	@50 L/min <0.8 cmH2O	@100 L/min <1.6 cmH2O	Equivalent
		0.2 cm H20	0.9 cm H20	0.2 cm H20	0.6 cm H20	0.2 cm H20	0.6 cm H20	
Breathing Resistance (cmH_2O) ISO 17510:2015 Annex E	Inspiratory	0.44 cm H20 @ 50L/min		0.6 cm H20 @ 50L/min				Equivalent
	Expiratory	0.60 cm H20 @ 50L/min		0.80 cm H20 @ 50L/min				Equivalent

AAV Operating Pressures ISO 17510:2015 Annex D	De-activation	1.5 cm H2O	2.0 cm H2O		Equivalent
	Activation	1.0 cm H2O	1.5 cm H2O		Equivalent
Design parameter or feature		**Predicate device:** AirFit F20, K170924	**Modified device:** AirFit F20 Mask System	**Modified device:** AirFit F20 NM Mask System	**Comments**
Flow generator setting on compatible ResMed CPAP and Bi-level flow generators.		"Full face"	"Full face"		Identical
Sound		Sound power level: 30 dBA Sound pressure level: 23 dBA	**Multi-hole vent** Sound power level: 30 dBA Sound pressure level: 22 dBA **Diffuser vent** Sound power level: 21 dBA Sound pressure level: 13 dBA		Equivalent
Operating and storage temperature		Operating temperature: 5°C to 40°C Storage temperature: -20°C to +60°C	Operating temperature: 5°C to 40°C Storage temperature: -20°C to +60°C		Identical
Magnetic Clips	Number of magnets	4	4	0	Equivalent
	Strength on the surface (mT)	< 400	< 400	N/A	
	Strength at 50mm distance (mT)	< 0.5	< 0.5	N/A	

Non-clinical data submitted:
Non-clinical verification and validation testing completed for the AirFit F20 and AirFit F20 NM Mask Systems demonstrated that the mask systems met all intended performance requirements. These included:

Applicable performance and safety tests in accordance with ISO 17510:2015 Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories:

- CO2 rebreathing (ISO 17510:2015 Annex F)
- 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)
- Vibration and noise (ISO 17510:2015 Annex G)

Other bench tests:

- Pressure performance testing
- Pressure accuracy and pressure swing performance
- Mechanical Integrity of the mask system before and after the following environmental tests:
    - Home cleaning
    - Transportation and Storage
    - Operation environment
    - Free fall and sit test
    - Reprocessing

Biocompatibility evaluation was assessed and/or conducted in accordance with ISO 18562-1 *Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process*, ISO 10993-1 *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process* and applicable regulatory guidance.

Validation of multi-patient re-use reprocessing claims (in accordance with ISO 17664-1 *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 17664-2 *Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices*, ST98 *Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices* and AAMI TIR12 *Designing, Testing, And Labeling Medical Devices Intended For Processing By Health Care Facilities: A Guide For Device Manufacturers*) included a combination of cleaning efficacy, disinfection efficacy, residual toxicity and mechanical integrity assessment/testing.

Verification confirmed that AirFit F20 and AirFit F20 NM Mask Systems met the predetermined acceptance criteria and the performance is substantially equivalent to the previously cleared predicate AirFit F20 Mask (K170924).

The AirFit F20 and AirFit F20 NM Mask Systems were assessed and/or tested in accordance with the applicable requirements in relevant FDA consensus standards including:

Standards	Title
ISO 17510:2015	Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories
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 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: Test for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
ISO10993-12:2021	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 10993-18:2021	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation
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
ISO17664-2:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.
ISO 5356-1:2015	Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
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

Substantial Equivalence Conclusion:

The AirFit F20 mask systems and AirFit F20 NM mask systems are substantially equivalent to the predicate AirFit F20 (K170924):

- They have equivalent intended use
- They have similar technological characteristics
- They have similar performance characteristics
- The differences do not raise any new questions of safety or effectiveness
- They are as safe and as effective as the predicate device