



April 29, 2026

BMC Medical Co., Ltd.
Nicole Niu
Regulatory Affairs Manager
Rm. 10, 17f, Bldg. 4, Huiya Plz., # 16 Lize Rd.
Fengtai District
Beijing, 100073
China

Re: K253166

Trade/Device Name: F6S Full Face Mask (F6S); P6S Nasal Pillows Interface (P6S)

Regulation Number: 21 CFR 868.5905

Regulation Name: Noncontinuous ventilator (IPPB)

Regulatory Class: Class II

Product Code: BZD

Dated: March 26, 2026

Received: March 26, 2026

Dear Nicole Niu:

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/pmnmn.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 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: 2026.04.29 17:00:48 -04'00'

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)

K253166

Device Name

F6S Full Face Mask (F6S); P6S Nasal Pillows Interface (P6S)

Indications for Use (Describe)

The Nasal Pillows Interface (P6S) is intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy. The Nasal Pillows Interface (P6S) is:

- to be used by patients (> 66 lbs. / 30 kg) for whom positive airway pressure therapy has been prescribed.
- intended for single-patient re-use in the home environment.

The Full Face Mask (F6S) is intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy. The Full Face Mask (F6S) is:

- to be used by patients (> 66 lbs. / 30 kg) for whom positive airway pressure therapy has been prescribed.
- intended for single-patient re-use in the home 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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Date Prepared: 23-March-2026

Sponsor: BMC Medical Co., Ltd
Room 10, 17F, Building 4, Huiya Plaza, No. 16 Lize Road,
Fengtai District,
Beijing, China

Submission Correspondent: Nicole Niu
Regulatory Affairs Manager
E-mail: niuxiaowei@bmc-medical.com
Tel: +86-10-5166 3880

Prepared and submitted by: Amy Wang
Regulatory Affairs Specialist
E-mail: wangliping@bmc-medical.com
Tel: +86-10-5166 3880

Proprietary or Trade Name: Full Face Mask (F6S) and Nasal Pillow Interface (P6S)
Common/Usual Name: CPAP Mask
Classification Name: Ventilator, Non-Continuous (Respirator)
Product Code: BZD

Predicate Device: DreamWear Silicone Pillows Mask - K210844
Common/Usual Name: CPAP Mask
Classification Name: Ventilator, Non-Continuous (Respirator)
Product Code: BZD

Predicate Device: AirFit F30i NM Mask System - K234134
Common/Usual Name: CPAP Mask
Classification Name: Ventilator, Non-Continuous (Respirator)
Product Code: BZD

Device Description:

The Full Face Mask (F6S) and the Nasal Pillows Interface (P6S) are both intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy. Both devices are used by patients (> 66 lbs./30 kg) for whom positive airway pressure therapy has been prescribed; and intended for single-patient re-use in the home environment.

As the device names indicate, the Full Face Mask provides a seal around the patient's nose and mouth, whereas the nasal pillows interface provides a seal at the entrance to the nares. Both devices



use a cushion assembly and a tube connection above the head. To breathe fresh air, the mask features vent holes in the cushion and elbow.

The mask is comprised of:

1. Cushion assembly
2. Tube
3. Elbow assembly
4. Headgear and Soft sleeves (optional accessory)

Principle of Operation:

Both the F6S Full Face Mask and P6S Nasal Pillows Interface are connected to a positive airway pressure device through breathing tube where the device channels airflow non-invasively to the patient.

Indications for Use:

The Nasal Pillows Interface (P6S) is intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy. The Nasal Pillows Interface (P6S) is:

- to be used by patients (> 66 lbs. / 30 kg) for whom positive airway pressure therapy has been prescribed.
- intended for single-patient re-use in the home environment.

The Full Face Mask (F6S) is intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy. The Full Face Mask (F6S) is:

- to be used by patients (> 66 lbs. / 30 kg) for whom positive airway pressure therapy has been prescribed.
- intended for single-patient re-use in the home environment.

Patient Population:

Patients (> 66 lbs. / 30 kg) for whom positive airway pressure therapy has been prescribed.

Environments of use:

Home environment

Biocompatibility

Biocompatibility testing was performed in accordance with the following standards:

- ISO 10993-5 – Cytotoxicity
- ISO 10993-10 – Sensitization
- ISO 10993-23 – Intracutaneous Reactivity
- ISO 10993-11 – Material Mediated Pyrogenicity
- ISO 18562-1 – Breathing Gas Pathway Devices Biocompatibility
- ISO 18562-2 – Particulate Matter Release
- ISO 18562-3 – VOCs Emissions with ISO 18562-1 for TRA
- ISO 18562-4 – Leachates in Condensates/ISO 10993-18 – Chemical characterization with ISO 18562-1/ISO 10993-17 for TRA

Non-clinical Testing

Performance testing demonstrated that the subject device met its acceptance criteria. Testing included, evaluation of deadspace, exhaust flow, pressure drop, CO₂ rebreathing, cleaning validation, aging, transportation, and sound power and pressure levels. All applicable tests were conducted in accordance with ISO 17510:2015 (Medical Devices for Sleep Apnea Breathing Therapy) and ISO 5356-1:2015, and ASTM D4169-22, confirming that both the F6S and P6S meet the applicable performance and safety requirements for their intended use.

**Substantial Equivalence Discussion****Indications for Use –**

The indications for use for the subject device Nasal Pillows Interface (P6S) is identical to the predicate.

The indications for use for the subject device Full Face Mask (F6S) has been slightly modified, but the change does not impact substantial equivalence predicate.

Discussion – There is no meaningful difference in the indications for use between the subject and predicate device – DreamWear Silicone Pillows Mask – K210844 and AirFit F30i NM Mask System – K234134.

Note: predicate AirFit F30i NM Mask System – K234134 had four models cleared in the original submission. We have removed references to the other device in that submission and claim substantial equivalence only to the AirFit F30i NM Mask System.

Technology and construction –

The technology and construction for both the subject device Nasal Pillows Interface (P6S) and Full Face Mask (F6S) are similar to the identified predicate devices.

The Full Face Mask (F6S) offers different size masks, but performance testing shows similar device performance when compared to the predicate. The predicate refers to a frame, which is similar to the subject device construction that is referred to as “tube”. The mask uses a cushion assembly that seals

under the nose (and around the mouth for the full-face mask) while the adjustable straps of the headgear hold the mask in place.

Discussion – The differences between the subject and predicate device DreamWear Silicone Pillows Mask – K210844 and AirFit F30i NM Mask System – K234134 – do not raise any new concerns of safety as the functional technology is similar.

Note: predicate AirFit F30i NM Mask System – K234134 had four models cleared in the original submission. We have removed reference to the other device in that submission and claim substantial equivalence only to the AirFit F30i NM Mask System.

Environment of Use –

The environment of use is identical.

Discussion – The environments of use are identical to the predicate – DreamWear Silicone Pillows Mask – K210844 and AirFit F30i NM Mask System – K234134.

Note: predicate AirFit F30i NM Mask System – K234134 had four models cleared in the original submission. We have removed references to the other device in that submission and claim substantial equivalence only to the AirFit F30i NM Mask System.

Patient Population –

The patient population of the subject device and predicate is identical.

Discussion – The patient population is equivalent to the predicate device – DreamWear Silicone Pillows Mask – K210844 and AirFit F30i NM Mask System – K234134.

Substantial Equivalence Conclusion

The performance and technological characteristics of the subject devices have demonstrated that they are substantially equivalent to the predicate devices – DreamWear Silicone Pillows Mask – K210844 and AirFit F30i NM Mask System – K234134. The differences do not raise new questions of safety and effectiveness.



510(k) Summary
Page 4 of 11

	Subject Device P6S Nasal Pillows Interface	Predicate Device DreamWear Silicone Pillows Mask	Comparison
Applicant	BMC Medical Co., Ltd.	Respironics, Inc.	/
K#	K253166	K210844	/
Product Code	BZD	BZD	Identical
CFR	21 CFR 868.5905	21 CFR 868.5905	Identical
Classification	II	II	Identical
Indications for Use	<p>The Nasal Pillows Interface (P6S) is intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy.</p> <p>The Nasal Pillows Interface (P6S) is:</p> <ul style="list-style-type: none"> - to be used by patients (> 66 lbs. / 30 kg) for whom positive airway pressure therapy has been prescribed. - intended for single-patient re-use in the home environment. 	<p>The DreamWear Silicone Pillows Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.</p>	<p>Similar</p> <p>We have slightly modified the indications language, but the change does not impact substantial equivalence</p>
Patient Population	Patients (>66 lbs./30kg)	Patients (>66 lbs./30kg)	Identical
Environment of Use	Home	Home or hospital/institutional environment	The subject device is not intended for use in the hospital/institutional environment
Patient Usage Type	Single patient re-use	Single patient use or multi patient use	The subject device is not intended for multi patient use
Anatomical Sites	Nose	Nose	Identical
Provided Sterile or Non-Sterile	Non-sterile	Non-sterile	Identical
Pressure Range Specification	4 to 25 cmH ₂ O	4 to 30 cm H ₂ O	Similar
Deadspace Volume	<p>S Tube</p> <p>S Cushion – 98 ml</p> <p>M Cushion – 99 ml</p> <p>L Cushion – 101 ml</p>	<p>S Frame</p> <p>S Cushion – 73 ml</p> <p>M Cushion – 74 ml</p> <p>MW Cushion – 75 ml</p> <p>L Cushion – 78 ml</p>	<p>Similar.</p> <p>Meet the requirements of ISO17510:2015.</p>



510(k) Summary
Page 5 of 11

	Subject Device P6S Nasal Pillows Interface	Predicate Device DreamWear Silicone Pillows Mask	Comparison														
	M Tube S Cushion – 101 ml M Cushion – 102 ml L Cushion – 104 ml	Medium Frame S Cushion – 76 ml M Cushion – 77 ml MW Cushion – 78 ml L Cushion – 81 ml															
	L Tube S Cushion – 107 ml M Cushion – 108 ml L Cushion – 110 ml	Large Frame S Cushion – 78 ml M Cushion – 80 ml MW Cushion – 81 ml L Cushion – 84 ml															
Pressure Drop	Drop in Pressure (for three size cushions): at 50 L/min: 0.5 cmH ₂ O at 100 L/min: 1.5 cmH ₂ O	Drop in Pressure (cm H ₂ O)	Similar. Meet the requirements of ISO17510:2015.														
		Cushion Size		at 50 SLPM													
				at 100 SLPM													
		<table border="1"> <tr> <td>S</td> <td>1.3</td> <td>4.8</td> </tr> <tr> <td>M</td> <td>1.2</td> <td>4.3</td> </tr> <tr> <td>L</td> <td>1.1</td> <td>3.8</td> </tr> </table>	S	1.3	4.8	M	1.2	4.3	L	1.1	3.8						
S	1.3	4.8															
M	1.2	4.3															
L	1.1	3.8															
Sound Power and Pressure Level	Measured Sound Pressure Level: 28dBA Measured Sound Power Level: 20dBA	Measured Sound Pressure Level: 27dBA Measured Sound Power Level: 19dBA	Similar														
Total Mask Leak	For three size cushions: <table border="1"> <tr> <td>Pressure (cmH₂O)</td> <td>4</td> <td>9</td> <td>12</td> <td>15</td> <td>20</td> <td>25</td> </tr> <tr> <td>Flow rate (L/min)</td> <td>17</td> <td>26</td> <td>31</td> <td>36</td> <td>43</td> <td>50</td> </tr> </table>	Pressure (cmH ₂ O)	4	9	12	15	20	25	Flow rate (L/min)	17	26	31	36	43	50	4 cm H ₂ O S Cushion – 18.4 SPLM M Cushion – 18.9 SPLM MW Cushion – 19.3 SPLM L Cushion – 19.6 SPLM 5 cm H ₂ O S Cushion – 21 SPLM M Cushion – 21.4 SPLM MW Cushion – 21.9 SPLM L Cushion – 22.3 SPLM 10 cm H ₂ O S Cushion – 31.7 SPLM M Cushion – 32.3 SPLM MW Cushion – 33.2 SPLM	Similar
Pressure (cmH ₂ O)	4	9	12	15	20	25											
Flow rate (L/min)	17	26	31	36	43	50											



510(k) Summary
Page 6 of 11

	Subject Device P6S Nasal Pillows Interface	Predicate Device DreamWear Silicone Pillows Mask	Comparison
		L Cushion – 32.9 SPLM 20 cm H ₂ O S Cushion – 48.9 SPLM M Cushion – 50.1 SPLM MW Cushion – 51.2 SPLM L Cushion – 49.5 SPLM 30 cm H ₂ O S Cushion – 64.8 SPLM M Cushion – 66.5 SPLM MW Cushion – 67.6 SPLM L Cushion – 64.4 SPLM	
CO2 Rebreathing (ETCO2%)	Results: Small Cushion with Large Tube 4 cm H ₂ O – 2.8% 5 cm H ₂ O – 2.2% 10 cm H ₂ O – -2.6% Results: Medium Cushion with Large Tube 4 cm H ₂ O – 3.0% 5 cm H ₂ O – 1.8% 10 cm H ₂ O – -2.4% Results: Large Cushion with Large Tube 4 cm H ₂ O – 4.2% 5 cm H ₂ O – 2.2% 10 cm H ₂ O – -2.4%	Results: MW Cushion with Large Frame 4 cm H ₂ O – 5.0% 5 cm H ₂ O – 5.0% 10 cm H ₂ O – 5.0%	Similar. Meet the requirements of ISO17510:2015.
Reprocessing Methods	Air path and non-air path components – Cleaning with liquid dish detergent	Air path and non-air path components – Cleaning with liquid dish detergent Air path components – High level chemical and thermal disinfection Non-air path components thermal disinfection	Similar. The cleaning method has been validated.



510(k) Summary
Page 7 of 11

	Subject Device P6S Nasal Pillows Interface	Predicate Device DreamWear Silicone Pillows Mask	Comparison
Cushion Design	A silicone nasal pillows cushion with tips that seal at the entrance to the nares. The cushion contains exhalation ports	A silicone nasal pillows cushion with tips that seal at the entrance to the nares. The cushion contains exhalation ports	Similar
Frame Design	The tube connects to nasal cushion; Two slots exist for insertion of headgear straps	The tubing frame connects to nasal cushion; Two slots exist for insertion of headgear straps, or headgear stabilizer arms	Similar
Exhalation/Exhaust	No separate exhalation device is required. Exhalation is built into the elbow and nasal cushions	No separate exhalation device is required. Exhalation is built into the elbow and nasal cushions	Similar
Headgear Design	Headgear's two straps connect to the Tube.	Headgear includes stabilizer arms that connect to the headgear strap and the slots on the mask frame.	Similar
Patient Circuit Connection	22 mm swivel connector	22 mm swivel connector	Identical
Sizes	One size headgear 3 nasal pillow cushion sizes: Small, Medium, Large The tube is available in three size: small, medium and large	One size headgear 4 nasal pillows cushion sizes: Small, Medium, Medium Wide, Large Three frame sizes: Small, Medium, Large	Similar



510(k) Summary
Page 8 of 11

	Subject Device Full Face Mask (F6S)	Predicate Device AirFit F30i Non Magnetic	Comparison
Applicant	BMC Medical Co., Ltd.	ResMed Corp.	/
K#	K253166	K234134	/
Product Code	BZD	BZD	Identical
CFR	21 CFR 868.5905	21 CFR 868.5905	Identical
Classification	II	II	Identical
Indications for Use	<p>The Full Face Mask (F6S) is intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy.</p> <p>The Full Face Mask (F6S) is:</p> <ul style="list-style-type: none"> to be used by patients (> 66 lbs. / 30 kg) for whom positive airway pressure therapy has been prescribed. intended for single-patient re-use in the home environment. 	<p>The AirFit F30i Non Magnetic variant is intended for single-patient reuse in the home environment.</p> <p>This mask is for patients weighing more than 66 lbs. (30 kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy.</p>	<p>Substantially Equivalent</p> <p>Note: We have removed the following models (AirFit F30i, AirFit F30i SLM, AirFit F30i Non Magnetic SLM, from the predicate device indications for use as we do not intend to claim to substantial equivalence to all models included in K234134.</p>
Patient Population	Patients weighing more than 66 lbs. (30 kg)	Patients weighing more than 66 lbs. (30 kg)	Identical
Environment of Use	Home	Home	Identical
Patient Usage Type	Single patient re-use	Single patient re-use	Identical
Anatomical Sites	Face	Face	Identical



510(k) Summary
Page 9 of 11

Provided Sterile or Non-Sterile	Non-sterile		Non-sterile		Identical
Pressure Range Specification	4 to 30 cmH ₂ O		4 to 30 cmH ₂ O		Identical
Deadspace Volume	Small Tube S Cushion – 234 ml M Cushion – 240 ml L Cushion – 242 ml MW Cushion – 243 ml		Small Frame S Cushion – 230 ml M Cushion – 235 ml SW Cushion – 240 ml W Cushion – 255 ml		Similar Meet the requirements of ISO17510:2015.
	Medium Tube S Cushion – 237 ml M Cushion – 243 ml L Cushion – 245 ml MW Cushion – 246 ml		Medium Frame S Cushion – 235 ml M Cushion – 240 ml SW Cushion – 245 ml W Cushion – 260 ml		Similar Meet the requirements of ISO17510:2015.
	Large Tube S Cushion – 243 ml M Cushion – 248 ml L Cushion – 251 ml MW Cushion – 252 ml		Large Frame S Cushion – 240 ml M Cushion – 245 ml SW Cushion – 250 ml W Cushion – 265 ml		Similar Meet the requirements of ISO17510:2015.
Pressure Drop (cm H₂O)	Flow (L/min)	Pressure (cm H ₂ O)	Flow (L/min)	Pressure (cm H ₂ O)	Similar Meet the requirements of ISO17510:2015.
	50	0.5	50	0.2	
	100	1.5	100	1.0	
Mask exhaust flow	Pressure (cm H ₂ O)	Flow (L/min)	Pressure (cm H ₂ O)	Flow (L/min)	Similar Meet the requirements of ISO17510:2015.
	4	22	4	22	
	11	39	11	38	
	12	41	17	48	
	17	49	24	59	
	24	59	30	67	
	30	67			
CO₂ Rebreathing (ETCO₂%)	F6S Small		Pressure (cm H ₂ O)	Relative CO ₂ increase	Similar Meet the requirements of ISO17510:2015.
	Pressure (cm H ₂ O)	Relative CO ₂ increase	4	7.7%	
	4hPa	0.0%	5	5.2%	
	5hPa	-3.00%			



510(k) Summary
Page 10 of 11

	<table border="1"> <tr> <td>10hPa</td> <td>-5.40%</td> </tr> <tr> <td colspan="2" style="text-align: center;">F6S Medium</td> </tr> <tr> <td>Pressure (cm H₂O)</td> <td>Relative CO₂ increase</td> </tr> <tr> <td>4hPa</td> <td>0.0%</td> </tr> <tr> <td>5hPa</td> <td>-1.80%</td> </tr> <tr> <td>10hPa</td> <td>-3.20%</td> </tr> <tr> <td colspan="2" style="text-align: center;">F6S Large</td> </tr> <tr> <td>Pressure (cm H₂O)</td> <td>Relative CO₂ increase</td> </tr> <tr> <td>4hPa</td> <td>-1.00%</td> </tr> <tr> <td>5hPa</td> <td>-3.00%</td> </tr> <tr> <td>10hPa</td> <td>-4.60%</td> </tr> <tr> <td colspan="2" style="text-align: center;">F6S MW</td> </tr> <tr> <td>Pressure (cm H₂O)</td> <td>Relative CO₂ increase</td> </tr> <tr> <td>4</td> <td>-1.00%</td> </tr> <tr> <td>5</td> <td>-5.00%</td> </tr> <tr> <td>10</td> <td>-5.80%</td> </tr> </table>	10hPa	-5.40%	F6S Medium		Pressure (cm H ₂ O)	Relative CO ₂ increase	4hPa	0.0%	5hPa	-1.80%	10hPa	-3.20%	F6S Large		Pressure (cm H ₂ O)	Relative CO ₂ increase	4hPa	-1.00%	5hPa	-3.00%	10hPa	-4.60%	F6S MW		Pressure (cm H ₂ O)	Relative CO ₂ increase	4	-1.00%	5	-5.00%	10	-5.80%	<table border="1"> <tr> <td>10</td> <td>1.5%</td> </tr> </table>	10	1.5%	
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Pressure (cm H ₂ O)	Relative CO ₂ increase																																				
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5	-5.00%																																				
10	-5.80%																																				
10	1.5%																																				
CO₂ Rebreathing (ETCO₂%) Single Fault Condition	<table border="1"> <tr> <td colspan="2" style="text-align: center;">F6S Small</td> </tr> <tr> <td>Condition</td> <td>Relative CO₂ increase</td> </tr> <tr> <td>Blockage of tube</td> <td>40.80%</td> </tr> <tr> <td>failure generate flow</td> <td>50.40%</td> </tr> <tr> <td colspan="2" style="text-align: center;">F6S Medium</td> </tr> <tr> <td>Condition</td> <td>Relative CO₂ increase</td> </tr> <tr> <td>Blockage of tube</td> <td>40.60%</td> </tr> <tr> <td>failure generate flow</td> <td>48.60%</td> </tr> <tr> <td colspan="2" style="text-align: center;">F6S Large</td> </tr> <tr> <td>Condition</td> <td>Relative CO₂ increase</td> </tr> <tr> <td>Blockage of tube</td> <td>40.80%</td> </tr> <tr> <td>failure generate flow</td> <td>51.00%</td> </tr> <tr> <td colspan="2" style="text-align: center;">F6S MW</td> </tr> <tr> <td>Condition</td> <td>Relative CO₂ increase</td> </tr> </table>	F6S Small		Condition	Relative CO ₂ increase	Blockage of tube	40.80%	failure generate flow	50.40%	F6S Medium		Condition	Relative CO ₂ increase	Blockage of tube	40.60%	failure generate flow	48.60%	F6S Large		Condition	Relative CO ₂ increase	Blockage of tube	40.80%	failure generate flow	51.00%	F6S MW		Condition	Relative CO ₂ increase	<table border="1"> <tr> <td>Condition</td> <td>Relative CO₂ increase</td> </tr> <tr> <td>Blockage of tube</td> <td>42.50%</td> </tr> <tr> <td>failure generate flow</td> <td>55.10%</td> </tr> </table>	Condition	Relative CO ₂ increase	Blockage of tube	42.50%	failure generate flow	55.10%	<p style="text-align: center;">Similar Meet the requirements of ISO17510:2015.</p>
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510(k) Summary
Page 11 of 11

	Blockage of tube failure generate flow	40.20% 49.60%			
Anti-Asphyxia Valve Pressure (cmH₂O)	Open Closed	< 4 cm H ₂ O < 4 cm H ₂ O	Open Closed	< 4 cm H ₂ O < 4 cm H ₂ O	Similar Meet the requirements of ISO17510:2015.
Inspiratory and expiratory resistance under single fault condition (cmH₂O)	Inspiratory Expiratory	0.4 0.2	Inspiratory Expiratory	0.2 0.4	Similar Meet the requirements of ISO17510:2015.
Sound	Sound power level: 26 dBA Sound pressure level: 18 dBA		Sound power level: 25 dBA Sound pressure level: 18 dBA		Similar Meet the requirements of ISO17510:2015.
Cushion Design	The mask uses a cushion assembly that seals under the nose (and around the mouth for the full-face mask offering) while the adjustable straps of the headgear hold the mask in place.		Oral nasal cradle cushion that seals under the nose and around the mouth		Similar
Reprocessing	Single patient re-use		Single patient re-use		Identical
Frame Design	Tubular conduit		Tubular conduit		Similar
Headgear Design	Available in one size Soft sleeves are optional		Available in one size		Similar
Exhaust Port Location	Elbow and cup		Elbow and cushion		Similar
Sizes	Small Medium Medium Wide Large		Small Cushion Medium Cushion Small Wide Cushion Wide Cushion		Similar
PAP tubing connection point	22mm conical connector as per ISO 5356-1 over the head connection		22mm conical connector as per ISO 5356-1 over the head connection		Identical