August 14, 2026

BMC Medical Co., Ltd.
Nicole Niu
Regulatory affairs manager
Rm. 10, 17f, Bldg. 4, Huiya Plaza
16 Lize Rd., Fengtai District
Beijing,
China

Re: K260171
Trade/Device Name: Portable Oxygen Concentrator (PO1 5B, PO1 6B)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: July 12, 2026
Received: July 13, 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/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 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,

Bradley Q. Quinn -S

Bradley Quinn
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260171

Please provide the device trade name(s).

Portable Oxygen Concentrator (PO1 5B, PO1 6B)

Please provide your Indications for Use below.

The device is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining. It is intended for both home healthcare environment and the professional healthcare facility environment. It is intended for adults only, prescription required.

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

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

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 878.4810.

1. Submitter's Information

Sponsor Name: BMC Medical Co., Ltd.
Address: Room 10, 17F, Building 4, Huiya Plaza, No.16 Lize Road, Fengtai District, 100073 Beijing, PEOPLE'S REPUBLIC OF CHINA
Contact Person: Nicole Niu
Tel: (86) 010-51663880
E-mail: niuxiaowei@bmc-medical.com

2. Subject Device Information

Trade Name: Portable Oxygen Concentrator
Model: PO1 5B, PO1 6B
Regulation: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW

3. Predicate Device Information

Sponsor: Inogen, Inc
Trade Name: Inogen Rove 6 Portable Oxygen Concentrator
Regulation: 21 CFR 868.5440
510(k) Number: K230052
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW

4. Device Description

The Portable Oxygen Concentrator (model: PO1 5B, PO1 6B) is a portable oxygen generator that provides supplemental oxygen to patients requiring oxygen therapy. It may be used in home healthcare environment and the professional healthcare facility environment. It is used with a nasal cannula to channel oxygen from the device to the patient. The concentrator and the nasal cannula are non-sterile. The Portable Oxygen Concentrator (model: PO1 5B, PO1 6B) uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the ambient air. Oxygen is delivered to the

patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserving technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed.

The Portable Oxygen Concentrator (model: PO1 5B, PO1 6B) utilizes Bluetooth technology that pairs the portable oxygen concentrator to a mobile device or tablet using the device.

All the technology parameters are the same for PO1 5B and PO1 6B, except that there is 5 levels of Flow Control Setting for PO1 5B with pulse oxygen flow of 0.20 L/min-1.00 L/min while 6 levels for PO1 6B with pulse oxygen flow of 0.20 L/min-1.20 L/min.

5. Intended Use and Indications for Use

The device is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining. It is intended for both the home healthcare environment and the professional healthcare facility environment. It is intended for adults only, prescription required.

6. Test Summary

6.1 Summary of Non-Clinical Performance Testing

Performance Testing Summary

The Portable Oxygen Concentrator (Model: PO1 5B, PO1 6B) has been thoroughly evaluated for electrical safety and performance and has been found to conform to the following standards.

1) Electrical safety and electromagnetic compatibility (EMC)

- IEC 60601-1: 2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances
- IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-11:2020 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-1-8: 2020 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

- ISO 80601-2-69: 2020 Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
- ISO 80601-2-67: 2020 Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment

2) Biocompatibility testing

- ISO 18562-1: 2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2: 2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3: 2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
- ISO 10993-17:2023. Biological Evaluation of Medical Devices - Part 17: Establishment of Allowable Limits for Leachable Substances

3) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions". Since a failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, basic level documentation was provided in this submission.

4) Cybersecurity

- Cybersecurity in Medical Devices： Quality System Considerations and Content of Premarket Submissions

5) Human Factor

- Applying Human Factors and Usability Engineering to Medical Devices

6）Battery Safety Testing

- IEC 62133-2: 2021 ,Secondary cells and batteries containing alkaline or other non-acid electrolytes－Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications－Part 2: Lithium systems.

6.2 Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

7. Comparison to predicate device and conclusion

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Verdict
Company	BMC Medical Co., Ltd.	Inogen, Inc.	--
Trade Name	Portable Oxygen Concentrator	Inogen Rove 6 Portable Oxygen Concentrator	--
Model	PO1 5B, PO1 6B	Inogen Rove 6)	--
510(k) Number	Applying	K230052	--
Product Code	CAW	CAW	Same
Device classification	Class II	Class II	Same
Regulation number	21 CFR 868.5440	21 CFR 868.5440	Same
Intended Use and Indications.	The device is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining. It is intended for both the home healthcare environment and the professional healthcare facility environment. It is intended for adults only, prescription required.	The Inogen Rove 6 Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, vehicle, and other transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.	Same Note 1
Prescriptive	Yes	Yes	Same
Fundamental scientific technology	● Breath detection technology ● Molecular sieve/pressure swing adsorption technology	● Breath detection technology ● Molecular sieve/pressure swing adsorption technology	Same
Patient use	Patients requiring supplemental oxygen	Patients requiring supplemental oxygen	Same
User/Patient Interface	User interface panel	User interface panel	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
	LCD Display to convey information about operating status in numbers and symbols.	LCD Display to convey information about operating status in numbers and symbols.	Same
	Alarm Indicator - yellow LED on main unit above Alarm Symbol that illuminates to indicate abnormal operating conditions in compliance with IEC 60601-1-8	Alarm Indicator - yellow LED on UIP above “Alarm/Warning” triangle symbol that illuminates to indicate abnormal operating conditions in compliance with ISO 60601-1-8	Same
	Auditory Speaker – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	Auditory Speaker – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	Same
	Filter -The filters must be always in place during operation to keep the air going into the device free of large particles.	Particle Filter -The filters must be always in place during operation to keep the air going into the device free of large particles.	Same
	Optional accessories - Extended battery, DC adapter, Carry bag	Optional accessories - Carry Bag, Backpack, Cart, External Battery Charger	Similar Note 2
	Respiration Data Management Software (PAP Link App) - Optional mobile application for viewing oxygen concentration, flow setting, total running time.	Inogen Connect Mobile Application - Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French.	Similar Note 3
Operating system	Software monitored	Software monitored	Same
Bluetooth technology	PAP Link App - Connection to Android or iPhone The Portable Oxygen Concentrator (model: PO1 5B, PO1 6B) is capable of Bluetooth functionality with the PAP Link App.	Inogen Connect App - BLE Connection to Android or iPhone. The Inogen Rove 6 Oxygen Concentrator is capable of Bluetooth functionality with the Inogen Connect App	Same
Components	AC/DC Power Adapter - Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.	AC/DC Power Adapter - Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.	Same
	DC Power Cable – cord and adapter to allow for connection to 12VDC-24VDC outlet with cigarette lighter connector and barrel jack connection to concentrator	DC Power Cable – cord and adapter to allow for connection to 12-volt DC outlet with cigarette lighter connector and barrel jack connection to concentrator	Similar Note 4
	Battery – utilizes an 8 or 16-cell lithium battery. To attach the battery, slide it on to the base of the	Battery – utilizes an 8 or 16-cell lithium battery. To attach the battery, slide it on to the base of the	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
	concentrator. Battery release latch – Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.	concentrator. Battery release latch – Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.	
Size	185 mm×83 mm×220 mm (with standard battery) 185 mm×83 mm×240 mm (with extended battery)	183 mm×83 mm×205 mm (with standard battery) 183 mm×83 mm×229 mm (with extended battery)	Similar Note 5
Principle of Operation	The Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through air intake filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an oxygen tank. Waste nitrogen is exhausted back into the ambient air. Sieve beds, control valve, sensor and embedded software are used to control the cycle to make the system function. Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserving technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the oxygen tank into the connected nasal cannula and on to the patient.	The Inogen Rove 6 Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function. Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. Inogen Rove 6 Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient.	Same
Performance			
Oxygen delivery mode	Pulse dose	Pulse dose	Same

<table>
<tr><th>Elements of Comparison</th><th>Subject Device</th><th>Predicate Device</th><th>Verdict</th></tr>
<tr>
<td>Output flow</td>
<td>PO1 5B
<table>
<tr><th>Breaths per minute</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th><th>Setting 5</th></tr>
<tr><td>15</td><td>13.3</td><td>26.7</td><td>40.0</td><td>53.3</td><td>66.7</td></tr>
<tr><td>20</td><td>10.0</td><td>20.0</td><td>30.0</td><td>40.0</td><td>50.0</td></tr>
<tr><td>25</td><td>8.0</td><td>16.0</td><td>24.0</td><td>32.0</td><td>40.0</td></tr>
<tr><td>30</td><td>6.7</td><td>13.3</td><td>20.0</td><td>26.7</td><td>33.3</td></tr>
<tr><td>35</td><td>5.7</td><td>11.4</td><td>17.1</td><td>22.9</td><td>28.6</td></tr>
<tr><td>40</td><td>5.0</td><td>10.0</td><td>15.0</td><td>20.0</td><td>25.0</td></tr>
<tr><td>Total volume per minute (ml/min)</td><td>200</td><td>400</td><td>600</td><td>800</td><td>1000</td></tr>
</table>
PO1 6B
<table>
<tr><th>Breaths per minute</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th><th>Setting 5</th><th>Setting 6</th></tr>
<tr><td>15</td><td>13.3</td><td>26.7</td><td>40.0</td><td>53.3</td><td>66.7</td><td>80.0</td></tr>
<tr><td>20</td><td>10.0</td><td>20.0</td><td>30.0</td><td>40.0</td><td>50.0</td><td>60.0</td></tr>
<tr><td>25</td><td>8.0</td><td>16.0</td><td>24.0</td><td>32.0</td><td>40.0</td><td>48.0</td></tr>
<tr><td>30</td><td>6.7</td><td>13.3</td><td>20.0</td><td>26.7</td><td>33.3</td><td>40.0</td></tr>
<tr><td>35</td><td>5.7</td><td>11.4</td><td>17.1</td><td>22.9</td><td>28.6</td><td>34.3</td></tr>
<tr><td>40</td><td>5.0</td><td>10.0</td><td>15.0</td><td>20.0</td><td>25.0</td><td>30.0</td></tr>
</table>
</td>
<td>
<table>
<tr><th>Breaths per minute</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th><th>Setting 5</th><th>Setting 6</th></tr>
<tr><td>10</td><td>21.0</td><td>42.0</td><td>63.0</td><td>84.0</td><td>105.0</td><td>126.0</td></tr>
<tr><td>15</td><td>14.0</td><td>28.0</td><td>42.0</td><td>56.0</td><td>70.0</td><td>84.0</td></tr>
<tr><td>20</td><td>10.5</td><td>21.0</td><td>31.5</td><td>42.0</td><td>52.5</td><td>63.0</td></tr>
<tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td><td>42.0</td><td>50.4</td></tr>
<tr><td>30</td><td>7.0</td><td>14.0</td><td>21.0</td><td>28.0</td><td>35.0</td><td>42.0</td></tr>
<tr><td>35</td><td>6.0</td><td>12.0</td><td>18.0</td><td>24.0</td><td>30.0</td><td>36.0</td></tr>
<tr><td>40</td><td>5.25</td><td>10.5</td><td>15.75</td><td>21.0</td><td>26.3</td><td>31.5</td></tr>
<tr><td>Total volume per minute (ml/min)</td><td>210</td><td>420</td><td>630</td><td>840</td><td>1050</td><td>1260</td></tr>
</table>
</td>
<td>Similar

Note 6</td>
</tr>
</table>

Elements of Comparison	Subject Device	Predicate Device	Verdict
	Total volume per minute (ml/min) 200 400 600 800 1000 1200		
Oxygen purity	93%±3% at all settings	90% -3%/+6% at all settings	Similar Note 7:
Maximum Limited pressure	⩽ 195kPa	< 28.9 PSI (199 kPa)	Similar Note 8
Performance standards			
Performance electrical safety and EMC	IEC 60601-1: 2020 IEC 60601-1-2: 2020 IEC 60601-1-6: 2020 IEC 60601-1-8: 2020 IEC 60601-1-11: 2020 ISO 80601-2-69: 2020 ISO 80601-2-67: 2020	IEC 60601-1:2012 IEC 60601-1-2: 2012 IEC 60601-1-6: 2020 IEC 60601-1-8: 2012 IEC 60601-1-11: 2015 ISO 80601-2-69: 2020 ISO 80601-2-67: 2020	Similar Note 9.
Biocompatibility	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2024 Particulate matter ISO 18562-3: 2024 Volatile organic compounds	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2017 Particulate matter ISO 18562-3:2017 Volatile organic compounds	Similar Note 10.

Comparison in Detail(s):

Note 1:

The subject device can be used in home healthcare which is the same as predicate device, and it meets the environmental requirement for professional healthcare facility environment based on the IEC 60601-1-2. Therefore, this difference will not raise safety or effectiveness issue.

Note 2:
Though the optional accessories of subject device is a little different from the predicate device, the difference will not raise any safety or effectiveness issue.

Note 3:
Though the information displayed on APP is different from predicate device, the user can just view such information, but cannot make any changes to the setting on the APP. So, the displayed information on APP will not have effect on the performance of the device.

Note 4:
The voltage of the DC power is a little different from the predicate device, but the subject device meets the requirement of IEC 60601-1, IEC 60601-1-11 and ISO 80601-2-69. So, this difference will not raise safety or effectiveness issues.

Note 5:
The size of subject device is a little different from the predicate device, but it will not raise safety or effectiveness issues。

Note 6:
The output flow of PO1 6B is very close to the predicate device, and the output flow of PO1 5B is within the range or PO1 6B. And the device meets the requirement of ISO 80601-2-69 and ISO 80601-2-67. So, this slight difference will not raise safety or effectiveness issue.

Note 7:
The oxygen purity of subject device is within the range of predicate device, and the subject device meets the requirement of ISO 80601-2-69 and ISO 80601-2-67. So, the slight difference will not raise safety or effectiveness issues.

Note 8:
The maximum output pressure is close to the predicate device, and the subject device meets the requirement of ISO 80601-2-69 and ISO 80601-2-67. So, the slight difference will not raise safety or effectiveness issues.

Note 9:
Both the subject device and predicate device meet the requirement of same standards, and the subject device meets the requirement of the latest standards. So, the difference of version will not raise the safety or effectiveness issues.

Note 10:
Both the subject device and predicate device meet the requirement of the same standards, and the subject device meets the requirement of the latest standards. So, the difference of version will not raise the safety or effectiveness issues.

Final Conclusion:

The subject device is as safe, as effective, and performs equivalently to or better than the legally marketed predicate device K230052.

8. Date of the summary prepared: August 13, 2026