July 30, 2026

Salter Labs
% Tanja-Maria Ranta
Advisor, Regulatory Management
Airlife Finland OY
Kuortaneenkatu 2
Helsinki, Uusimaa 00510
Finland

Re: K261389
Trade/Device Name: PRO2 Elite Plus Oxygen Analyzer (PRO2PLUS-1)
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: Class II
Product Code: CCL
Dated: July 6, 2026
Received: July 6, 2026

Dear Tanja-Maria Ranta:

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.	K261389

Please provide the device trade name(s).

PRO2 Elite Plus Oxygen Analyzer (PRO2PLUS-1)

Please provide your Indications for Use below.

The PRO2 Elite Plus Oxygen Analyzer is intended as a tool to be used by qualified personnel to spot-check oxygen concentration, flow, and pressure of a delivered air/oxygen mixture of an oxygen concentrator. The Oxygen Analyzer is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes hospitals, nursing homes, extended care facilities, patient homes, and respiratory device service and repair centers. The Oxygen Analyzer is not intended for use in continuous monitoring of oxygen delivery to patients.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

Attachment 10.2 510(k) Summary

Contents

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AirLife™

510 (K) Summary
Initial Submission

Date of Submission prepared: 27 April 2026

I. Manufacturer: Salter Labs

Address: 30 Spur Drive, El Paso, TX 79906, United States
Telephone: 01-616-2598373
Email: ryamashita@myairlife.com
Official Contact: Robert Yamashita / VP of Regulatory Affairs
FDA Establishment Registration Number: 3004748541

II. Subject Device

Trade name:	PRO2 Elite Plus Oxygen Analyzer
Model:	Pro2PLUS-1
Regulation Number:	21 CFR 868.1720 Oxygen gas analyzer
Product Code:	CCL - Analyzer, Gas, Oxygen, Gaseous-Phase
Medical Specialty:	Anesthesiology
Regulatory Class:	Class II

III. Predicate Device

Trade name:	UltraMax O2 Oxygen Analyzer
510 (k) Number	K112402
Regulation Number:	21 CFR 868.1720 Oxygen gas analyzer
Product Code:	CCL - Analyzer, Gas, Oxygen, Gaseous-Phase
Medical Specialty:	Anesthesiology
Regulatory Class:	Class II

IV. Device Description

The PRO2 Elite PLUS™ Oxygen Analyzer is intended for spot-checking oxygen concentration, flow, and pressure of a delivered air/oxygen mixture of an oxygen concentrator. It is not intended for continuous monitoring of oxygen delivery to patients.

The PRO2 Elite PLUS™ Oxygen Analyzer is a micro-processor controlled handheld device designed for testing the functionality of an oxygen concentrator, for example during routine maintenance. It is connected to the output port of the oxygen concentrator via a connection tube. After the concentrator's output stabilizes, the oxygen analyzer is turned on. It can measure the enriched gas's oxygen concentration (%), flow (LPM), and pressure (kPa or PSI). The measured parameters are displayed on the device's screen. The device does not store the

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values. The analyzer can be changed from oxygen concentration and flow mode to pressure measurement mode by sliding the switch on the side of the device.

To verify the calibration of the subject device's oxygen/flow sensor, it can be connected to a pure oxygen (100%) source. Using the source button, the user can set the device to "pure O2" mode and compare the reading to the known content of the bottle.

V. Indications for use

The PRO2 Elite Plus™ Oxygen Analyzer is intended as a tool to be used by qualified personnel to spot-check oxygen concentration, flow, and pressure of a delivered air/oxygen mixture of an oxygen concentrator. The Oxygen Analyzer is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes hospitals, nursing homes, extended care facilities, patient homes, and respiratory device service and repair centers. The Oxygen Analyzer is not intended for use in continuous monitoring of oxygen delivery to patients.

VI. Equivalence Comparison to the Predicate Device

See Tables 1 and 2 in Annex A below for detailed comparison.

VII. Performance test

PRO2 Elite PLUS™ Oxygen Analyzer complies with the following consensus standards:

- ISO 80601-2-55 Second edition 2018-02 [Including AMD1:2023] *[FR Recognition No. 1-184]*
  Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitor [Including Amendment 1 (2023)].

- ANSI AAMI ISO 14971: 2019 *[FR Recognition No. 5-125]*
  Medical devices - Application of risk management to medical devices

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION *[FR Recognition No. 19-49]*
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] *[FR Recognition No. 19-36]*
  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]

- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION *[FR Recognition No. 19-38]*
  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

- ANSI AAMI IEC 62304:2006/A1:2016 *[FR Recognition No. 13-79]*
  Medical device software - Software life cycle processes [Including Amendment 1 (2016)]

- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION *[FR Recognition No. 5-132]*
  Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION *[FR Recognition No. 5-129]*
  Medical devices - Part 1: Application of usability engineering to medical devices

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VIII. Conclusion

The subject device (PRO2 Elite PLUS™ Oxygen Analyzer Model: PRO2PLUS-1) and the predicate (UltraMaxO2 Oxygen Analyzer) are handheld, battery-powered ultrasonic oxygen analyzers. Both devices are intended to be used in an environment where oxygen concentrators are being serviced or repaired.
Both Devices:

- Have the same intended use, same fundamental measurement technology and same measurement capabilities.
- Use ultrasonic time-of-flight measurement as technology for O2 measurements.
- Measure oxygen concentration by analyzing transit time of ultrasonic pulses.
- Measure flow using upstream/downstream ultrasonic signal differentials.
- Measure pressure via an internal pressure sensing mechanism.
- Display measured values on an LCD interface.
- Atmospheric Pressure and Humidity are similar. The Subject device operating pressure range is slightly wider than predicate device to be compliant with the requirements of ANSI/AAMI HA60601-1-11.
- Flow measurement ranges are similar. Subject device has a minimum measurement capability of 0.5 LPM. Although the subject device has a different flow range compared to the predicate device, the flow range for the subject device is within the cleared range of the predicate.

Both devices consist of piezo-electric ultrasonic transducers, injection molded structural components, and common PCBA materials / integrated circuit components. The control mechanism on both devices is a firmware controlled microprocessor. The subject device and the predicate device have minor technical and operational differences. The subject device (PRO2 Elite PLUS™ Oxygen Analyzer Model: PRO2PLUS-1) performs as well or better than the predicate device (UltraMaxO2 Oxygen Analyzer). Based on comparisons of technical and safety features, and comparative performance evaluations, the proposed PRO2 Elite PLUS™ Oxygen Analyzer device is substantially equivalent to the predicate UltraMaxO2 Oxygen Analyzer.

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IX. Annex A - Comparison to the Predicate Device

TABLE 1: MAIN ATTRIBUTES COMPARISON OF SUBJECT DEVICE PRO_2 ELITE PLUS™ VERSUS PREDICATE DEVICE ULTRAMAXO2

Attributes	**PRO_2 Elite PLUS™ Oxygen Analyzer** Model: PRO2PLUS-1	**UltraMaxO_2 Oxygen Analyzer K112402**	**Remarks**
Intended Use	The PRO2 Elite Plus Oxygen Analyzer is intended as a tool to be used by qualified personnel to spot-check oxygen concentration, flow, and pressure of a delivered air/oxygen mixture of an oxygen concentrator.	The UltraMaxO_2 Oxygen Analyzer is a tool used to measure oxygen purity, flow and pressure at the outlet of an oxygen concentrator.	The intended uses are materially the same. Indications for use are materially the same.
Indications for Use	The Oxygen Analyzer is intended to be used in an environment where oxygen concentrators are being serviced or repaired. The Oxygen Analyzer is not intended for use in continuous monitoring of oxygen delivery to patients.	The UltraMaxO_2 Oxygen Analyzer is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes hospitals, nursing homes, extended care facilities, patient homes, and respiratory device service and repair centers.	
Principle of Operation	The O_2 analyzer detects oxygen concentration and flow rate using ultrasonic transducers. The pressure is measured using a pressure sensor.	The UltraMax O2 Oxygen Analyzer measures oxygen concentration and flow using ultrasound technology and measures pressure using a piezoresistive silicon pressure sensor.	Same
Intended User	Service technician Delivery technician Biomedical equipment technician Respiratory therapist	Professional use	The professional intended users are materially the same.
Intended Use Environment	Hospitals, nursing homes, extended care facilities, patient homes, and respiratory device service and repair centers.	Hospitals, nursing homes, extended care facilities, patient homes, and respiratory device service and repair centers.	The environments where the professional users operate are materially the same.
Atmospheric Pressure	70 to 106 kPa (700 - 1060 mbar hPa)	80-100 kPa 800 - 1000 mbar (hPa)	Similar. The Subject device operating pressure range is slightly wider than that of predicate device to comply with the requirements of ANSI/AAMI HA60601-1-11 subclause 4.2.3.1.
Humidity	5-90% non-condensing	0-95% non-condensing	Similar. The subject device has a slightly narrower range for relative humidity than the predicate. The range for proposed device complies with requirements of ANSI/AAMI HA60601-1-11 subclause 4.2.3.1.
Electrical Requirements	2 x AA Alkaline batteries (2 x 1.5 Volts)	2 x AA Alkaline batteries (2 x 1.5 Volts)	Identical.
Operating Temperature Range	15˚C - 40˚C (59˚F-104˚F)	15˚C - 40˚C (59˚F-104˚F)	Identical.
Storage Temperature Range	-15˚C - 60˚C (5˚F-140˚F)	-15˚C - 60˚C (5˚F-140˚F)	Identical.

Attributes	PRO$_2$ Elite PLUS™ Oxygen Analyzer Model: PRO2PLUS-1	UltraMaxO$_2$ Oxygen Analyzer K112402	Remarks
Mode of Operation	Continuous	Continuous	Identical.
Electrical Classification:	Internally powered Medical Electrical equipment	Internally powered Medical Electrical equipment	Identical.
Protection against water	IP22	IPX1	Similar. Subject device was tested to more challenging ingress protection (IP) requirements for residential environments per ANSI/AAMI HA60601-1-11 Clause 8.3.1.
Measurement Capability - Oxygen Measurement Range	20.9- 96%	20.9- 96%	Identical.
Oxygen Measurement Resolution	0.1% Oxygen	0.1% Oxygen	Identical.
Oxygen Measurement Accuracy	± 1.5% Full Scale (at constant temp. & optimal flow)	±-1.5% Full Scale (at constant temp. & optimal flow)	Identical.
Measurement Capability - Flow Measurement Range	0.5 - 10 LPM	0 - 10 LPM	Similar. Subject device has a minimum measurement capability of 0.5 LPM. Although the subject device has a slightly different flow range, the flow range is within the cleared range of the predicate.
Flow Measurement Resolution	0.1 LPM	0.1 LPM	Identical.
Flow Measurement Accuracy	±0.2 LPM	±0.2 LPM	Identical.
Measurement Capability - Pressure Measurement Range	0.5 - 50 (PSI), 3.4 - 344 (kPa)	0.5 - 50 (PSI), 3.4 - 344 (kPa)	Identical.
Pressure Measurement Resolution	0.1 (PSI), 0.1 up to 199, 1 from 200 to 344 (kPa)	0.1 (PSI), 0.1 up to 199, 1 from 200 to 344 (kPa)	Identical.
Pressure Measurement Accuracy	±0.5% (PSI), ±0.5% (kPa)	±0.5% (PSI), ±0.5% (kPa)	Identical.
Response Time:	≤10 seconds	≤17 seconds	Similar. The subject device has an improved response time compared to the predicate.
Warm-up Time:	< 1 second	< 1 second	Identical.
Low Battery Indication:	Low battery icon displayed on graphics screen	Low battery icon displayed on graphics screen	Identical.
Battery life	≥ 1,100 hours (16,500 read cycles)	≥ 1,100 hours (16,500 read cycles)	Identical.

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Attributes	PRO$_2$ Elite PLUS™ Oxygen Analyzer Model: PRO2PLUS-1	UltraMaxO$_2$ Oxygen Analyzer K112402	Remarks
Sensor Type	Ultrasonic	Ultrasonic	Same
Sensor Life	Device lifetime	Device lifetime	Identical.
Drift of Measurement:	Within accuracy specifications. No need for field calibration.	Within accuracy specifications. No need for field calibration.	Identical.
Alarms	None	None	Identical.

TABLE 2: COMPARISON OF OTHER SPECIFICATIONS FOR SUBJECT DEVICE PRO$_2$ ELITE PLUS™ VERSUS PREDICATE DEVICE ULTRAMAXO2

Attributes	PRO$_2$ Elite PLUS™ Oxygen Analyzer Model: PRO2PLUS-1	Predicate: UltraMaxO$_2$ Oxygen Analyzer K112402	Remarks
Interface	Two buttons: On\Off and Source. Pressure channel switch	Two buttons: On\Off and Mode. Pressure channel switch	Similar.
Controls	ON/OFF button O_2 Source button Mode switch (Oxygen & Flow mode or pressure mode) Pressure unit button	ON/OFF button Mode button Gas sample outlet (blocking it with finger triggers pressure measurement) Pressure unit switch	Similar. The subject and predicate device have the same primary features. The subject device has a different means for switching between modes.
Display	PSI indicator Kpa Indicator Lpm indicator % indicator Low battery symbol 3 digits and 1 decimal 2 digits and 1 decimal O_2 concentrator indicator Pure oxygen indicator	PSI indicator Kpa Indicator Lpm indicator % indicator Low battery symbol 3 digits and 1 decimal 2 digits and 1 decimal	Similar. The subject device's display includes the same fields/icons as the predicate device. The subject device integrates two additional icons for indicating which mode is active to the user.
Battery cover	Battery cover locked in place with a spring-loaded lever. No tool needed for removing battery cover.	Battery cover locked in place using a small screw. Tool/screwdriver needed for removing battery cover.	Similar. The subject device does not require a tool for removing the battery cover/ changing the batteries. ESD testing per ISO 60601-1-2 was performed to subject device with battery cover removed.
Weight	125 g (without batteries)	181 g	When accounting for the weight of the batteries, the weights of the devices are very similar and suitable for the user population.
Dimensions	64.9 mm x 144.5 mm x 22.5 mm	80.3 mm x 129.5 mm x 26.5 mm	Sizes are similar and suitable for use in the use environment.
EMC Emissions Compliance	Group 1 Class B	Group 1 Class A	Different. The subject device was tested to a more challenging CISPR 11 Class B requirements for residential environments per ANSI/AAMI HA 60601-1-11 Clause 12.