



April 24, 2025

Life Spark Medical, LLC
Darryl Zitting
Biomedical Engineer
2430 W 350 N
Washington, Utah 84737

Re: K250002

Trade/Device Name: Smart Check O2 (MA0236)
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: Class II
Product Code: CCL
Dated: December 30, 2024
Received: January 2, 2025

Dear Darryl Zitting:

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
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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)

K250002

Device Name

Smart Check O2 (MA0236)

Indications for Use (Describe)

The Smart Check O2 is a tool used to measure oxygen purity, flow and pressure at the outlet of an oxygen concentrator. The Smart Check 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K250002

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Contact Person

Darryl Zitting

Date Summary Prepared

Mar-27-2025

Subject Device Trade Name

Smart Check O2

Common Name

Oxygen Gas Analyzer

Classification

Analyzer, Gas, Oxygen, Gaseous-Phase (21 CFR 868.1720, Product Code CCL, Class 2)

Predicate Device

Maxtec Ultramax Oxygen Analyzer, 510(k) # K112402

Subject Device Description

The Smart Check O2 is an ultrasonic oxygen analyzer, used to verify the performance of oxygen concentrators. The device is typically used by durable medical equipment technicians while servicing concentrators in their workshops or while visiting patient homes, but it is not left with the patient and is not patient contacting.

The device measures the performance of the oxygen concentrator by making ultrasonic time-of-flight measurements, both upstream and downstream. Gas flow rate and oxygen concentration are determined using the resulting data. Temperature and pressure sensors inside the sample cell allow for accurate flow and oxygen readings over the range of specified operating environment conditions.

Oxygen and flow readings are shown to the user on the display. The Smart Check O2 can be toggled into a mode for testing pulsing (conserving) oxygen concentrators wherein it displays oxygen concentration and pulse volume instead of flow rate. The user may initiate a pressure check mode by stopping the sample exhaust port with their finger during which the Smart Check O2 measures and displays the maximum pressure generated by the concentrator. The user may also enter a calibration check mode and deliver pure oxygen to the Smart Check O2 to verify its performance. However, it does not require regular calibration after manufacturing.

The Smart Check O2 is for prescription use only.

Key Components:

- Handheld analyzer unit
- Removable battery door
- Replaceable sample tube
- Two Alkaline AA cells

Key Performance Characteristics

All key performance characteristics are listed in the subsequent Substantial Equivalence Comparison Table.

Indication for Use Statement

The Smart Check O2 is a tool used to measure oxygen purity, flow and pressure at the outlet of an oxygen concentrator. The Smart Check 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.

Technological Characteristics

The technological characteristics of the Smart Check O2 are substantially equivalent to the predicate device including:

Physical Form: Handheld

Energy Source: Battery operated

Method of operation: Ultrasonic, upstream/downstream time-of-flight measurement

Control Mechanism: Firmware controlled microprocessor

Material composition: Piezo-electric ultrasonic transducers, injection molded structural components, and common PCBA materials / integrated circuit components.

Non-Clinical Performance Data

The Smart Check O2 complies with the following consensus standards:

ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021]

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 60601-1-11:2015 MOD) [Including Amendment1 (2021)]

ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]

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)]

ISO 80601-2-55 Second edition 2018-02 [Including AMD1:2023]

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitor [Including Amendment 1 (2023)]

Substantial Equivalence Comparison Table	Subject Device (K250002)	Predicate device (K112402)	Comparison	Does the difference raise new questions of safety and effectiveness?
Model:	Smart Check O2	UltraMaxO2		
Manufacturer:	Life Spark Medical	Maxtec		
Product Code:	CCL (Class 2) - Analyzer, Gas, Oxygen, Gaseous-Phase	CCL (Class 2) - Analyzer, Gas, Oxygen, Gaseous-Phase	Same	No
Patient Population:	Not for use on patients, only oxygen concentrators.	Not for use on patients, only oxygen concentrators.	Same	No
Indications for Use:	The Smart Check O2 is a tool used to measure oxygen purity, flow, and pressure at the outlet of an oxygen concentrator. The Smart Check 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 UltramaxO2 Oxygen Analyzer is a tool used to measure oxygen purity, flow, and pressure of an oxygen concentrator. The UltraMaxO2 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.	Same	No
User Interface:	Input: Tactile dome switches (buttons) Output: Segmented LCD with backlight	Input: Tactile dome switches (buttons) Output: Segmented LCD without backlight	Similar	No: Improved visibility in low light without adding risks.
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.	Same	No

Substantial Equivalence Comparison Table	Subject Device (K250002)	Predicate device (K112402)	Comparison	Does the difference raise new questions of safety and effectiveness?
Concentrator Compatibility:	Continuous flow concentrators and pulsing (conserving) concentrators.	Continuous flow concentrators only.	New feature using same technology.	No: See following Substantial Equivalence Discussion.
Oxygen Measurement Range: (concentrator)	20.9 - 96%	20.9 - 96%	Same	No
Oxygen Measurement Accuracy:	+/- 1.5%	+/-1.5%	Same	No
Oxygen Measurement Resolution:	0.1%	0.1%	Same	No
Flow Measurement Range:	0-10LPM	0-10LPM	Same	No
Flow Measurement Accuracy:	+/-0.2 LPM	+/-0.2 LPM	Same	No
Flow Measurement Resolution:	0.1 LPM	0.1 LPM	Same	No

Substantial Equivalence Comparison Table	Subject Device (K250002)	Predicate device (K112402)	Comparison	Does the difference raise new questions of safety and effectiveness?
Pressure Measurement Range:	0 - 40 PSI	0.5 - 50 PSI	Similar	No: The highest pressure generated by concentrators, currently on the market, is 35 psi. Future concentrators offering higher supply pressures are not anticipated due to patient safety considerations.
Pressure Measurement Accuracy:	+/-0.5% of reading	+/-0.5% of reading	Same	No
Pressure Measurement Resolution:	0.1 PSI	0.1 PSI	Same	No
Pulse Volume Measurement Range:	3 - 200 ml	Does not measure pulse volume	New feature using same technology.	No: See Substantial Equivalence Discussion.
Pulse Volume Measurement Accuracy:	+/- 3 ml	Does not measure pulse volume	New feature using same technology.	No: See Substantial Equivalence Discussion.

Substantial Equivalence Comparison Table	Subject Device (K250002)	Predicate device (K112402)	Comparison	Does the difference raise new questions of safety and effectiveness?
Pulse Volume Measurement Resolution:	0.1 ml up to 100 ml, 1 ml above 100 ml	Does not measure pulse volume	New feature using same technology.	No: See Substantial Equivalence Discussion.
Response Time:	10 seconds	≤17 seconds	Similar	No: Subject device response time is improved compared to predicate.
Start-up (Warm-up) Time:	2.5 seconds	< 1 second	Similar	No: No new risks associated with adding 1.5 seconds to the analyzer boot-up time.
Operating Temperature:	5°C - 40°C	15°C - 40°C	Incremental Improvement	No: Subject device operating temp. range is wider, and compliant with the requirements of ANSI/AAMI HA60601-1-11 subclause 4.2.3.1.

Substantial Equivalence Comparison Table	Subject Device (K250002)	Predicate device (K112402)	Comparison	Does the difference raise new questions of safety and effectiveness?
Storage Temperature:	-25°C - 70°C	-15°C - 60°C	Incremental Improvement	No: Subject device storage temp. range is wider, and compliant with the requirements of ANSI/AAMI HA60601-1-11 subclause 4.2.2
Atmospheric Pressure:	700 – 1060 hPa (mbar)	800 - 1000 mbar (hPa)	Similar	No: Subject device operating pressure range is wider, and compliant with the requirements of ANSI/AAMI HA60601-1-11 subclause 4.2.3.1.
Humidity:	0 - 90% (non-condensing)	0 - 95% (non-condensing)	Similar	No: Subject device operating humidity range is compliant with the requirements of ANSI/AAMI HA60601-1-11 subclause 4.2.3.1.
Power Source:	2x AA Alkaline Batteries	2x AA Alkaline Batteries	Same	No
Battery Life:	> 16,000 read cycles	16,500 read cycles	Same	No

Substantial Equivalence Comparison Table	Subject Device (K250002)	Predicate device (K112402)	Comparison	Does the difference raise new questions of safety and effectiveness?
Dimensions:	75 mm x 147 mm x 27 mm	80.3 mm x 129.5 mm x 26.4 mm	Similar	No: Sizes of predicate and subject devices are very similar and both suitable for the use environment. No new risks associated with the minor differences in size.
Weight:	230 g	181 g	Similar	No: Weight of predicate and subject devices are similar and both suitable for the user population. No new risks associated with the minor differences in weight.

Substantial Equivalence Comparison Table	Subject Device (K250002)	Predicate device (K112402)	Comparison	Does the difference raise new questions of safety and effectiveness?
Electromagnetic Emissions compliance:	Group 1, Class B	Group 1, Class A	Similar	No: Subject device was tested to the more challenging CISPR 11 Class B requirements for residential environments per ANSI/AAMI HA60601-1-11 clause 12.
Ingress rating:	IP22	IPX1	Incremental Improvement	No: Subject device complies with the more stringent ingress rating requirements for residential environments per ANSI/AAMI HA60601-1-11 subclause 8.3.1.

Substantial Equivalence Discussion and Conclusion

The Smart Check O2 is substantially equivalent in environment, user population, application and performance when compared to the predicate device. Minor differences, as noted by “similar” or “incremental improvement” in the comparison column of the table, exist primarily as a result of direct compliance with the recommendations of the homecare standard ANSI/AAMI HA60601-1-11. All noted differences are minor and do not result in new or increased risks.

Pulse Mode:

In addition to displaying % oxygen and continuous flow rate, the subject device can calculate and display pulse volume, for pulsing (“conserving”) concentrators, using multiple flow reading measurements. This feature is not significantly different than measuring continuous flow rate because it uses the exact same measurement methods and technology to make repeated flow measurements, then calculates the additional data (pulse volume) by integrating flow rate over the time period of the pulse. This difference does not introduce new or different risks compared to the predicate.

The conclusions drawn from the non-clinical tests (discussed above) demonstrate that the device is substantially equivalent to the predicate device.