January 23, 2023

DEHAS Medical Systems GmbH
% Tom Hirte
Senior Director, Regulatory Affairs
Draeger Medical Systems GmBH
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K221494
Trade/Device Name: Quality Mix Blender, Oxymixer
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: Class II
Product Code: BZR
Dated: December 19, 2022
Received: December 22, 2022

Dear Tom Hirte:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

James J. Lee -S

James J. Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221494

Device Name
Quality Mix Blender, Oxymixer

Indications for Use *(Describe)*
The air-oxygen mixer Quality Mix is used to administer a continuous, precise mix of medical air and medical oxygen – through its outlet ports – to infants, children and adults. The exact fractional inspiratory oxygen concentration (FiO2) corresponds to the selected FiO2 setting on the control knob (dial).

It is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician in professional healthcare settings.

This product is not intended for use as a life supporting device.

Warning: By using flows above 70 LPM, the risk of high flow such as air trapping, barotrauma, and gastric insufflation (leading to possible aspiration) can occur.

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.

8 510(K) SUMMARY

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: January 12, 2023

Type: Traditional 510(k)

510(K) Number: K221494/S001

8.1. Submitter

DEHAS Medical Systems GmbH

Wesloer Straße 107-109

23568 Luebeck, Germany

Primary contact person

Jens Mittendorf

Managing Director / Head of Engineering & Development

Phone: +49-451-80904-200

Fax: +49-451-80904-111

E-Mail: J.Mittendorf@dehas.de

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule" …. 510(k) Summaries and 510(k) Statements…." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

8.2. Device

Device trade name: Quality Mix blender, Oxymixer

Common name: Breathing gas mixer

Classification name: Anesthesia Inhalation, Breathing Gas Mixer (21 CFR 868.5330)

Regulatory Class: II

Product Code : BZR

Models:

Quality Mix Low Flow, range 3-30 liters per minute

Quality Mix Low Flow XL, range 3-30 liters per minute

Quality Mix High Flow, range 15-120 liters per minute

Quality Mix High Flow XL, range 15-120 liters per minute

8.3. Predicated device equivalence

DEHAS Medical Systems GmbH is claiming substantial equivalence to the **Precision Blender (K053232) from Precision Medical Inc.**

8.4. Indications for use

The air-oxygen mixer Quality Mix is used to administer a continuous, precise mix of medical air and medical oxygen – through its outlet ports – to infants, children and adults. The exact fractional inspiratory oxygen concentration (FiO2) corresponds to the selected FiO2 setting on the control knob (dial).

It is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician in professional healthcare settings.

This product is not intended for use as a life supporting device.

Warning: By using flows above 70 LPM, the risk of high flow such as air trapping, barotrauma, and gastric insufflation (leading to possible aspiration) can occur.

8.5. Patient Group

The Quality Mix blender may be used on equipment where patient population is infant, pediatric and adult patients.

8.6. Environments of use

Professional healthcare settings, where the delivery and monitoring of air/ oxygen mixtures is required.

8.7. Device description

The air-oxygen blender Quality Mix is a compact air/oxygen mixing device, which provides a precise mixing of medical grade air and oxygen gases. The blender is a pneumatic powered device with flowmeters which can be connected to outlet ports to regulate the gas flow.

The Quality Mix series medical air / oxygen blender includes following models: Quality Mix High Flow; Quality Mix High Flow XL and Quality Mix Low Flow; Quality Mix Low Flow XL.

The Quality Mix series air / oxygen blender is designed, tested and manufactured in accordance with the standard ISO 11195:2018 Gas mixers for medical use – Stand – alone gas mixers.

8.8. Technology

The Quality Mix blender is designed to use two gas sources of medical air and oxygen (46,41– 94,27 psi). The two gas sources enter through the diameter – indexed air and oxygen inlet connectors located on the bottom of the Quality Mix blender. Once through the filters, each gas passes through a duckbill check valve which prevents possible reverse gas flow from either the oxygen or the air supply systems. The two gases then pass

through a two-stage balance regulator module. The purpose of this regulator module is to equalize the operating pressures of the air and oxygen gas sources.

Once these pressures have been balanced, the gases are proportioned according to the oxygen concentration selected on the oxygen concentration selection dial. The oxygen concentration dial allows the clinician to select a desired oxygen concentration from 21% to 100% O2.

When the pressure difference between the two inlet gases exceeds the prescribed value, or if there is a gas supply failure of one of the gas sources because of disconnection, the bypass poppet will move to one site and create a path for the high-pressure gas to flow into the alarm. This triggers the audible alarm. From this point, the mixed gas flows to the outlet port. The bleed valve on the auxiliary outlet port needs to be activated to ensure the oxygen concentration accuracy of ±3% when the intended output flow in low flow applications is below the specified range of ≤15 lpm for the High Flow blender and ≤3 lpm for the Low Flow blender.

8.9. Determination of substantial equivalence

The subject device has the same indication for use, the same patient group, and the same environment of use as the predicate device Precision Blender (K053232).

The subject device also has the same technological characteristics for example design components, the same function and uses the same energy source as the predicate device. Both devices accept room air and 100% oxygen gas and adjust the molar fraction of oxygen gas in the room air by mechanical means, and blended gas is supplied to the patient. They have identical specifications for the delivery of blended gas and they use the same technology for the audible alarm if the pressure differential between the two inlet gases exceeds the prescribed value or if one gas source is disconnected. Both devices are pneumatically powered only and they produce an audible alarm. The subject device and the predicate device are not intended to be used sterile, nor do either device contain electrical components. The subject device and the predicate device are provided in versions of High Flow and Low Flow blenders.

Please see the table below for more details.

Item / Manufacturer	**Quality Mix Blender** **DEHAS Medical Systems GmbH** **Wesloer Str. 107-109** **23568 Luebeck, Germany**	**Quality Mix Blender** **DEHAS Medical Systems GmbH** **Wesloer Str. 107-109** **23568 Luebeck, Germany**	**PRECISION BLENDER** **Precision Medical, Inc.®** **300 Held Drive, Northampton, PA 18067, USA**	**PRECISION BLENDER** **Precision Medical, Inc.®** **300 Held Drive, Northampton, PA 18067, USA**
Model	**Quality Mix High Flow; XL**	**Quality Mix Low Flow; XL**	**PM5200 High Flow**	**PM5300 Low Flow**

Item / Manufacturer	Quality Mix Blender DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Luebeck, Germany	Quality Mix Blender DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Luebeck, Germany	PRECISION BLENDER Precision Medical, Inc.® 300 Held Drive, Northampton, PA 18067, USA	PRECISION BLENDER Precision Medical, Inc.® 300 Held Drive, Northampton, PA 18067, USA
510 (K) Number	**K221494/S001**	**K221494/S001**	**(K053232)**	**(K053232)**
Product Code	**BZR**	**BZR**	**BZR**	**BZR**
Regulation Number	**21 CFR 868.5330**	**21 CFR 868.5330**	**21 CFR 868.5330**	**21 CFR 868.5330**
Patient Group	Infant, pediatric, and adult patients	Infant, pediatric, and adult patients	Infant, pediatric and adult patients	Infant, pediatric, and adult patients
Primary Outlet Flow Range	15 – 120 LPM	3-30 LPM	15 – 120 LPM	3-30 LPM
	With both supply pressures at 50 psi (3,4 bar) with BLEED closed		With both supply pressures at 50 psi (3,4 bar) with BLEED closed	
Auxiliary Outlet Flow Range	15 – 120 LPM	3-30 LPM	15 – 120 LPM	3-30 LPM
	With both supply pressures at 50 psi (3,4 bar) with BLEED closed		With both supply pressures at 50 psi (3,4 bar) with BLEED closed	
	0 – 105 LPM	0 – 27 LPM	2-100 LPM	0-30 LPM
	With both supply pressures at 50 psi (3,4 bar) with BLEED open		With both supply pressures at 50 psi (3,4 bar) with BLEED open	
Bleed Flow	≤ 13 LPM at 50 psi (3,4 bar)	≤ 3 LPM at 50 psi (3,4 bar)	13 LPM or less at 50 psi (3,4 bar)	3 LPM or less at 50 psi (3,4 bar)
Maximum Combined Flow (all outlets)	≥ 120 LPM	≥ 30 LPM	≥ 120 LPM	≥ 30 LPM
Bypass Flow (loss of air or oxygen supply)	> 85 LPM	> 15 LPM	> 85 LPM	> 45 LPM
Bypass Alarm Activation (range of activation if	At inlet Pressure 46,41 psi (3,2 bar)	At inlet Pressure 46,41 psi (3,2 bar)	50 psi (3,45 bar) 13,25 – 25 psi (0,9 – 1.7 bar)	50 psi (3,45 bar) 18 – 22 psi (1.2 – 1.5 bar)

Item / Manufacturer	Quality Mix Blender DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Luebeck, Germany	Quality Mix Blender DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Luebeck, Germany	PRECISION BLENDER Precision Medical, Inc.® 300 Held Drive, Northampton, PA 18067, USA	PRECISION BLENDER Precision Medical, Inc.® 300 Held Drive, Northampton, PA 18067, USA
there is a pressure difference between both gas sources or loss of gas supply)	When pressure difference of one inlet gas is detected of ≥ 13,05 psi (≥ 0,9 bar).	When pressure difference of one inlet gas is detected of ≥ 13,05 psi (≥ 0,9 bar).		
	At inlet Pressure 60,92 psi (4,2 bar) When pressure difference of one inlet gas is detected of ≥ 13,05 psi (≥ 0,9 bar).	At inlet Pressure 60,92 psi (4,2 bar) When pressure difference of one inlet gas is detected of ≥ 13,05 psi (≥ 0,9 bar).	60 psi (4.14 bar) 16 – 24 psi (1.1 – 1.65 bar)	60 psi (3,.5 bar) 16 – 24 psi (1.1 – 1.65 bar)
	At inlet Pressure 94,27 psi (6,5 bar) When pressure difference of one inlet gas is detected of ≥ 13,05 psi (≥ 0,9 bar).	At inlet Pressure 94,27 psi (6,5 bar) When pressure difference of one inlet gas is detected of ≥ 13,05 psi (≥ 0,9 bar).		
Alarm Reset	When the pressure difference between the two inlet gases is restored to ≤ 4,35 psi (0,3 bar) to each other, the alarm will be reset.		When pressure differential is 6 psi (0.4 bar) or less	
Alarm Sound Level	≥ to 80 dB at a distance of 1 ft. (0,3 m)		≥ to 80 dB at 1 ft. (0,3 m)	
Oxygen Concentration Adjustment Range	21 – 100 %		21 – 100 %	
Gas Supply pressure	46,41– 94,27 psi (3,2 – 6,5 bar)		30 – 75 psi (2.1 – 5.2 bar)	

Item / Manufacturer	Quality Mix Blender DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Luebeck, Germany	Quality Mix Blender DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Luebeck, Germany	PRECISION BLENDER Precision Medical, Inc.® 300 Held Drive, Northampton, PA 18067, USA	PRECISION BLENDER Precision Medical, Inc.® 300 Held Drive, Northampton, PA 18067, USA
	Air and oxygen pressure differential should be within max 0.7 bar		Air and oxygen within 10 psi (0.69 bar) of each other	
Mixed Gas Stability	± 1% Oxygen		± 1% Oxygen	
Connection Types	DISS Type – air & oxygen inlets & outlets and / or NIST Type – air &oxygen inlets		DISS Type – air & oxygen inlets &outlets and / or NIST Type – air & oxygen inlets	
Dimensions	12.2” High x 16,5” Wide x 13” Deep [cm]		10.4” High x 5.7” Wide x 12.5” Deep [cm]	
Weight	1.6 kg		2.29 lbs. (1.04 kg)	
Shipping Weight	4.0 kg		2.95 lbs. (1.34 kg)	
Operating Temperature Range	41° F to 122°F (5°C to 50°C)		59° F to 104°F (15°C to 40°C)	
% Oxygen Control **Accuracy (FiO2)**	21-100% ± 3%	21-100% ± 3%	21 - 100% ± 3%	21-100% ± 3%
Normal operating pressure	air/ oxygen 46,41 – 94,27 psi	air/ oxygen 46,41 – 94,27 psi	air and oxygen 30 - 70 psi	air and oxygen 30 - 70 psi
Pressure Drop	High Flow: ≤ 0.21 bar at inlet pressures from 3,2 to 6,5 bar, with a flow rate of 30 LPM at 60% FiO2	Low Flow: ≤ 0.14 bar at inlet pressures from 3,2 to 6,5 bar, with a flow rate of 10 LPM at 60% FiO2	High Flow: ≤ 3 psi (0.21 bar) at 30-90 psi (2.1 – 6.2 bar) and at 30 LPM flow rate at 60% FiO2	Low Flow: ≤ 2 psi (0.14 bar) at 30-90 psi (2.1 – 6.2 bar) and at 10 LPM flow rate at 60% FiO2

Table 1: Table of comparison

The following quality assurance measures were applied to the development of the device:

- Risk analysis
- Requirements evaluation reports
- Raw materials verification
- Final acceptance testing requirements
- Performance testing verification

8.10. Summary of non – clinical tests

For comparison, we performed a number of non-clinical tests according to the equivalent standards to demonstrate that the subject device performs as intended and is substantial equivalent to the predicate device Precision Blender (K053232).

We used the following international standards for testing to demonstrate substantial equivalence:

Used Standard	Standard used for	Result: Pass /fail
ISO 11195:2018 (second edition) Gas mixers for medical use - Standalone gas mixers	ISO 11195:2018-01 Gas mixers for medical use - Stand-alone gas mixers (second edition) General Performance Test Report related to Standalone Blenders. This testing included applicable elements of the standard for blenders according clause 4 essential performance requirements: Clause 9: Reverse gas flow Clause 11: Alarm systems Clause 12: Accuracy of indicated oxygen concentration Clause 13: Gas supply failure	The Quality Mix Blender High Flow and Low Flow performs as intended within the specified functions and performance and fulfils the essential performance requirements clause 4 according to the standard ISO 11195:2018-01 for Gas mixers for medical use – Stand – alone gas mixers. **Result: pass**
ISO 14971 Second edition 2007-03-01 Medical devices -	This international standard has been used as a process for our medical devices for the	**Result: pass**

Application of risk management to medical devices FR Recognition List Number: 043 FR Recognition Number: 5-40	identification and assessment of hazards and associated risks, the control of these risks and the monitoring of the effectiveness of risk control measures.	
IEC 62366 – 1 Edition 1.0 2015-02 Medical devices Part 1: Application of usability engineering to medical devices (including CORRIGENDUM 1 2016) FR Recognition List Number: 046 FR Recognition Number: 5-114	This standard has been used to verify and validate the usability of the Quality Mix blender series.	Usability report Quality Mix blender series performed in cooperation with an authorized, certified competence center for medical oxygen blenders. **Result: pass**
German version EN 1789:2007+A2:2014 Medical vehicles and their equipment – Road ambulances German version EN 60068-2-6:2008 Environmental testing – Part 2-6: Tests – Test Fc: Vibration (sinusoidal) German version EN 60068-2-27:2009 Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock German version EN 60068-2-64:2008	We performed Laboratory Test with Report environmental testing regarding strength, vibration, shock of the device.	Vibration (sinusoidal) Test Shock Test Vibration, broadband random Test **Result: pass**

Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance		
DIN EN ISO 15002:2020-05 Flow-metering devices for connection to terminal units of medical gas pipeline systems	General performance test report for flow-metering devices for connection to blenders of Quality Mix Series (Compensated Thorpe tube flowmeter.	This testing included Flowmeter accuracy, Leak test, environmental and mechanical condition. **Result: pass**
ISO 15001:2010 Anesthetic and respiratory equipment - Compatibility with oxygen	The standard has been used to ensure the oxygen compatibility of the used materials.	Aspects of compatibility that are addressed include cleanliness, resistance to ignition and the toxicity of products of combustion and/or decomposition. **Result: pass**
ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process ISO 18562-2 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter ISO 18562-3 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds	Biocompatibility evaluation of breathing gas pathways in healthcare applications.	We did perform Biocompatibility testing: Gas emission VOC testing with a risk assessment of any identified chemical. Contact classification of blender: Indirect patient contact provided via the mixture of gases brought together by the blender and supplied to the patient (gas pathway contact), for medical devices with gas pathway contact to the patient, compliance to ISO 18562-1 is required Duration: The duration of use is classified as permanent (more than 30 days) within the scope of the standard ISO 18562-1

		Testing: The following biocompatibility tests were carried out: Tests for particulate matter emissions according to ISO 18562-2 Tests for volatile organic compound (VOC) emissions according to ISO 18562-3 **Result: pass**

Table 2: Summary of non - clinical tests

Conclusion:

In all cases the subject device passed or meets the acceptance criteria of general requirements for performance and basic safety. We can find the subject device substantially equivalent to the predicate device Precision Blender (K053232).

There are no differences which raise any different questions of safety and effectiveness.

8.11. Animal testing

No animal testing was performed.

8.12. Clinical tests

The subject of this premarket submission, Quality Mix blender series, do not require clinical studies to support substantial equivalence.

8.13. Discussion of Differences

There are a few differences between the subject device and the predicate device Precision Blender (K053232). The differences between the predicate and the subject device are addressed when we compare the subject device to the reference devices

They are:

Environments MRI

The environments of use of the Quality Mix series are same as the predicate device Precision Blender (K053232). But the Subjected Device is not for use in MRI Environments, due to the use of ferrous materials / metallic components. Therefore the Device as stated in the safety information's and labeling is marked as MR unsafe. The predicate Device Precision Blender (K053232) can be used in MRI environments of only 3 Tesla MR Systems. Both devices are not intended to be used sterile.

Physical characteristics:

Regarding the dimensions and weight, the physical characteristics are similar. All devices have been physically designed and evaluated to be used in clinical settings for their intended use.

Auxiliary outlet flow range (with both supply pressures at 50 psi (3,4 bar) with Bleed Flow open):

The specification of the auxiliary outlet flow range of the air-oxygen blender QualityMix series (High Flow, Low Flow) is similar to the predicate blender devices. The Low Flow and the High Flow blender require a minimum flow rate depending on the model if the auxiliary outlet is in use at low flow applications. This bleed flow is necessary to ensure the concentration accuracy ±3 % when using the blender on this outlet port for low flows, typically below ≤3 lpm (Low Flow blender) and below ≤15 lpm (High Flow blender). Therefore the bleed flow in low flow applications must be activated on this outlet port. Because of this necessary bleed flow, the flow rate in this application on the auxiliary outlet port ensures with an accuracy of ±3 % 0-27 lpm for Quality Mix Low Flow and 0 -105 lpm for Quality Mix High Flow blenders.

The predicate device ensures under same conditions an auxiliary outlet flow range of 0-30 lpm (Low Flow) and 2-100 lpm (High Flow) with an accuracy of ± 3%.

Bypass flow (loss of air or oxygen supply):

Regarding specification of the bypass flow of the Air Oxygen blender Quality Mix Series (High Flow, Low Flow) the performance is similar to the predicate blender devices.

The Quality Mix blender series has an alarm / bypass function, which guarantees a flow of > 85 LPM for the High Flow blenders and > 15 LPM for the Low Flow blenders in emergency situations, if one of the gas supply sources has a malfunction or loss.

The predicate device insures under same conditions a bypass flow of > 85 LPM for the High Flow blender and >45 LPM for the Low Flow blender.

Technical function of bypass flow of the subject device and the predicate device is the same. The bypass flow function ensures that the flow of the remaining gas is maintained, if other one of the two gas supply sources is malfunctioning and the remaining gas supply is at the indicated supply pressure value of normal operating condition.

At both devices, the gas bypass function operates in unison with the alarm. Once the pressure alarm is activated, the bypass function is actuated and the gas with the higher pressure flows directly to the outlet port, bypassing the mixing function of the blender. The oxygen concentration flowing out of the blender will be that of gas with the higher pressure.

Therefore, both devices meet the requirements of the ISO 11195 standard in the case of gas supply failure conditions.

Bypass alarm activation:

The difference is, that the alarm function of the subject device is more sensitive than the predicate device to inform the user of pressure differentials between medical air and medical oxygen. This safety mechanism was taken into account during the development and risk analysis and tested during the usability assessment. In this case, the alarm of the subject device arises at any inlet pressure range of tested normal operating conditions in

a case of a difference in pressure (O2 and Air) of≥13,05psi (0,9 bar) of the used gases and cease again before the difference in pressure drops below the value of ≤4,35 psi (≤0,3 bar).

The alarm of the predicate device Precision Blender (K053232) arises under tested normal operating conditions at a pressure difference between both gases between ≥16 - 24 psi (1.1 – 1.65 bar).Furthermore, the alarm function of the predicate device is infected and reacts by any different inlet pressure range.

Gas supply pressure / normal operating pressure of the blender:

Regarding normal operating pressure, the subject device was tested and specified within 46,41 – 94,27 psi (3,2 – 6,5 bar) inlet pressure of both gases. The predicate device Precision Blender (K053232) within 30 – 75 psi (2.1 – 5.2 bar). This difference does not raise any questions of safety and effectiveness. Both blenders have been tested by verification and meet the requirements of ISO 11195: 2018 that the gas blenders must cover and work in the entire nominal range of medical gas pipeline systems for compressed medical gases and vacuum according to ISO 7396-1 in hospital environments.

Operating temperature:

The operating temperature of the subject device is similar to the predicate device.

The operating temperature of the subject device is +5C° - +50C°.

The operating temperature of the predicate Precision Blender (K053232) device is 15C° – 40C°.

Pressure drop:

In comparison and according to the technical data and performance test, the subject device has similar performance of pressure drop in the range of ≤ 3 psi with a flow rate of 30 l/ min at 60% FiO2 (High Flow) and ≤ 2 psi with a flow rate of 10 l/ min at 60% FiO2 (Low Flow) at a set inlet pressure of 46,41 – 94,27 psi (3,2 – 6,5 bar).

The predicate device has a performance of pressure drop in the range of ≤ 3 psi with a flow rate of 30 l/ min at 60% FiO2 (High Flow) and ≤ 2 psi with a flow rate of 10 l/ min at 60% FiO2 (Low Flow) at a set inlet pressure of 2.1 – 6.2 bar (normal operating conditions).

The Quality Mix blenders has nearly the same performance specifications as the predicate device. The only difference is the specified range of the optimal and used inlet pressure under normal operating conditions.

8.14. Substantial equivalence conclusion

The subject device has the same intended use as the predicate device, and the technological differences do not raise different questions of safety and effectiveness.