October 29, 2024

DEHAS Medical Systems GmbH
% Darlene Thibodeau
Vice President, Quality Assurance and Regulatory Affairs
Draeger Medical Systems Inc.
6 Tech Drive
Andover, Massachusetts 01810

Re: K241366
Trade/Device Name: QualityFlow O2 Series (QualityFLOW O2); QualityFlow O2 Series (QualityFLOW O2 MTV)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: May 14, 2024
Received: May 14, 2024

Dear Darlene Thibodeau:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241366

Device Name
QualityFlow O2 Demand Valve (QualityFLOW O2)

Indications for Use *(Describe)*
The demand valve is used for the application of 100 vol% oxygen during manual ventilation with the resuscitator bag, as well as during direct non-invasive inhalation with the resuscitator mask in spontaneously breathing patients.
CAUTION:
Federal law restricts this device to sale by or on the order of a physician

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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8 510(K) SUMMARY

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

Date: October 25, 2024

Type: Traditional 510(k)

8.1 Submitter

DEHAS Medical Systems GmbH
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23568 Luebeck, Germany

Primary contact person
Jens Mittendorf
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8.2 Device Name

Proprietary / device trade name: QualityFlow O2 Demand Valve
Common name: Valve, Non-rebreathing
Classification name: 868.5870 Non-rebreathing Valve
Models:
D-DV-W QualityFlow O2 Demand Valve

8.3 Predicated device equivalence

DEHAS Medical Systems GmbH is claiming substantial equivalence to the **SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE (K953349) from Spiracle Technology, 10601 Calle Lee # 190, Los Alamitos, CA 90720.**

8.4 Indications for Use (IFU)

The demand valve is used for the application of 100 vol% oxygen during manual ventilation with the resuscitator bag, as well as during direct non-invasive ventilation with the resuscitator mask in spontaneously breathing patients.

CAUTION:

Federal law restricts this device to sale by or on the order of a physician

Comparison of Indications for use (IFU)

Old	New
The demand valve is used for the application of 100 vol% oxygen during manual ventilation with the resuscitator bag, as well as during direct non-invasive inhalation with the resuscitator mask in spontaneously breathing patients. WARNING: This device is not a resuscitator. This Device is not suitable for invasive use on the tube. This device should be used solely as an assessor with a bag valve resuscitator or a mask via compatible adapters. CAUTION: Federal law restricts this device to sale by or on the order of a physician	The demand valve is used for the application of 100 vol% oxygen during manual ventilation with the resuscitator bag, as well as during direct non-invasive ventilation with the resuscitator mask in spontaneously breathing patients. CAUTION: Federal law restricts this device to sale by or on the order of a physician

Response to Changes in the Indications for Use (IFU) Statement

In response to FDA requirements, we have revised the Indications for Use (IFU) statement for the demand valve to ensure clarity and consistency with the predicate device (Spiracle Technology OX – series, HFOC High Flow Oxygen Conserver Model No. 301, K953349). The changes focus on refining the intended use and removing unnecessary limitations to support better understanding and safe use of the device.

Removal of Restrictive Warnings

- **Rationale**: The original IFU included warnings such as “This device is not a resuscitator,” “This device is not suitable for invasive use on the tube,” and “This device should be used solely as an assessor….” These statements have been removed to avoid potential misunderstandings, as the demand valve is designed to provide manual ventilation with a resuscitator bag and non-invasive ventilation for spontaneously breathing patients, similar to the predicate device. By removing these warnings, the IFU now accurately reflects the actual intended use of the device without introducing unnecessary restrictions to its capabilities.

Clarification of Indications for Use (IFU)

- The revised IFU now clearly specifies that the demand valve is intended for the application of 100% oxygen during manual ventilation with the resuscitator bag,

as well as non-invasive ventilation with the resuscitator mask for spontaneously breathing patients. This refined description establishes a clear distinction from invasive ventilation, ensuring that the device's intended use is accurately and consistently described according to FDA requirements and the predicate device.

Retention of Legal Caution Statement

- The legally required statement that restricts the sale of the device to those with a physician's order ("Federal law restricts this device to sale by or on the order of a physician") remains unchanged to comply with legal requirements and ensure safe use.

Summary These changes ensure that the IFU accurately and clearly defines the demand valve's intended use by removing unnecessary limitations and aligning with FDA requirements and the predicate device.

8.5 Patient Group

The Valve, Non-rebreathing QualityFlow O2 demand valve may be used on equipment where patient population is children and adults.

8.6 Environments of use

Emergency care, Emergency medical Service (EMS), hospital and anaesthesie settings.

8.7 User group

Emergency care professionals, hospital respiratory care practitioners, anesthesiologists

8.8 Device description

The valve, non – rebreathing QualityFlow O2 demand valve is a medical device to deliver medical oxygen or a medical air – oxygen mixture to a patient on demand. Unlike continuous oxygen systems, the demand valve only supplies medical gas when the patient inhales, reducing oxygen consumption and ensuring the patient receives gas only when needed.

The demand valve is intended for the following methods of respiratory support:

Method: Demand Valve with Resuscitation Bag:

Function of the Demand Valve: When combined with a resuscitation bag, the demand valve controls the flow of oxygen when the patient is breathing spontaneously. The valve only releases oxygen or air when the patient inhales. The resuscitation bag, can be used to provide manual ventilation in case the patient is unable to breathe on their own.

Application: If the patient is breathing spontaneously, the resuscitation bag remains in standby and can be manually compressed to provide emergency ventilation. Meanwhile, the demand valve automatically supplies oxygen as needed without requiring manual intervention while the patient breathes independently.

Method: Demand Valve with Resuscitation Bag:

Function of the Demand Valve: The mask is placed over the patient's face and connected to the demand valve. The valve delivers oxygen through the mask when the patient inhales and closes during exhalation to prevent gas loss.

Application: This configuration is ideal for patients who are breathing on their own but require supplemental oxygen. The mask ensures a tight seal around the airways, allowing the demand valve to function efficiently. The patient receives only the required amount of gas, minimizing wastage and ensuring higher efficiency.

Three adapter are available for connecting the demand valve to the most common ventilation bags or masks.

Method: Demand Valve and Air – Oxygen Blender:

Function of the Demand Valve: The air-oxygen blender mixes ambient air with oxy-gen to create a specific oxygen concentration (FiO_2). This mixture is then delivered to the demand valve, which provides the blended gas to the patient only during inhalation.

Application: The blender ensures that the patient receives an exact oxygen concentration, which is delivered via the demand valve. The demand valve releases the gas only during the patient's inhalation, improving efficiency and reducing gas consumption. This setup is particularly useful in clinical situations where precise oxygen delivery is required.

The QualityFlow O2 demand valve is provided in the following model:

Version	Description	Picture
D-DV-W	QualityFlow O2 Demand Valve	

Table 1: Models QualityFlow O2 demand valve

8.9 Technology

The Valve, Non-rebreathing QualityFlow O2 Demand Valve (also known as a non-rebreathing valve) is a specialized airway device used in patients who have difficulty breathing adequately or who require controlled breathing. It is a device that delivers a controlled amount of medical oxygen to the patient based on the patient's breathing needs. The QualityFlow O2 Demand Valve from DEHAS consists of a membrane that is activated by negative pressure during inspiration and a valve mechanism that controls gas flow. During inspiration, the valve opens due to the movement of the membrane, while during expiration it is closed by a return spring.

The function of the demand valve is based on providing gas only when a negative pressure is applied to the membrane, e.g. by the patient inhaling with a connected mask or suction of the resuscitator when connected (expansion after previous compression of the resuscitator). The valve therefore ensures that gas only flows when it is needed.

The demand valve can be in 3 states:

Resting state: When the patient does not inhale, the valve is closed. The return spring holds the diaphragm in a position that closes the exhaust valve.

Inhalation: When the patient inhales, a negative pressure is created. This negative pressure tightens the membrane, which opens the outlet valve and allows gas to flow through.

Exhalation: When exhaling, the pressure acting on the membrane becomes positive, causing the return spring to push the membrane back to its original position and close the exhaust valve. This prevents the gas from flowing further.

The flow of the Valve, Non-rebreathing QualityFlow O2 is pressure controlled.

8.10 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 SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE (K953349).

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 SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE (K953349).

Please see the table below for more details.

Item / Manufacturer	**QualityFlow O2 demand valve** **DEHAS Medical Systems GmbH** **Wesloer Str. 107-109** **23568 Luebeck, Germany**	**SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE** **Spiracle Technology** **A FERNO Group Company** **10601 Calle Lee #190** **Los Alamitos, CA 90720**
Product family	**QualityFlow O2 Demand Valve**	**Spiracle Technology OX – series**
Model	**D-DV-W**	**HFOC High Flow Oxygen Conserver Model No. 301**
510 (K) Number	**K241366**	**(K953349)**
Product Code	**CBP**	**CBP**
Regulation Number	**21 CFR 868.5870**	**21 CFR 868.5870**
Patient Group	Adults and children	Children and Adults
Environments of use	Emergency care, hospital environment	Emergency care, hospital
User Group	Emergency care professionals, hospital respiratory care practitioners, anesthesiologists	Emergency care professionals, hospital respiratory care practitioners, anesthesiologists
Gas source	100 % medical oxygen	100 % medical oxygen
Pressure Trigger	- 0,5 to -1,2 cm H2O	0 to 0,5 cm H2O (standard)
Maximum Flow	Nominal ≥160 liters per minute	Nominal 160 liters per minute
Pressure relief	Ambient pressure conditions	Ambient pressure conditions
Demand mode	Yes	Yes
Oxygen inlet gas pressure	2,8 bar - 5,5 bar (40,61 - 79,8 psig)	2,7 bar – 6,2 bar (40 – 90 psig)
Operating temperature	-20°C up to +70°C (-4° F up to +158°F)	-30° to 125°F (-34° to 52°C)
Storage temperature	-20°C up to +40°C (-4°F up to +104° F)	-40° to 160°F (-40° to 71°C)
Dimensions	4,9 cm diameter x 56 mm (width incl. inlet) x 79 mm (height)	4,74 cm diameter x 57,9 mm (width incl. inlet) x 70,8 mm (height)

Item / Manufacturer	QualityFlow O2 demand valve DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Luebeck, Germany	SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE Spiracle Technology A FERNO Group Company 10601 Calle Lee #190 Los Alamitos, CA 90720
Weight	153 gram	270 gram
Inlet fitting	Standard inlet fitting male oxygen diss	Standard inlet fitting male oxygen diss
Outlet fitting	Thread for connecting a conical adapter according to ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets	Thread for connecting a conical adapter according to ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
Available accessories		
Medical oxygen hose	According to ISO 5359 Fourth edition 2014-10-01 Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases [Including AMENDMENT 1 (2017)]	According to ISO 5359 Fourth edition 2014-10-01 Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases [Including AMENDMENT 1 (2017)]
Adapter	according to ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones	according to ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones
Adapter Size	QualityFlow O2 Demand Valve Adapter:	HFOC Resuscitator Adapter:
	P/N: D – 2522002 26/31 mm I.D. / O.D. adapter	P/N: 2522002 26/31 mm I.D. / O.D. adapter
	P/N: D – DAN-252200 15/22 mm I.D. / O.D. adapter	P/N: 2522003 15/22 mm I.D./O.D. internal ribbed adapter
	P/N: D – 2522001 23/28 mm I.D. / O.D. adapter	P/N: 2522004 23/28 mm I.D. / O.D. adapter

Table 2: 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

8.11 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 SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE (K953349).

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

Used Standard	Standard used for	Result: Pass /fail
ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets FR Recognition List Number: 028 FR Recognition Number: 1-62	This ISO 5356-1:2004 standard was used to specify the dimension and dimensional requirements specified in the standard for cones and bushings intended for the connection of anesthesia and ventilator equipment, e.g. B. in ventilation systems, anesthetic gas transport systems and vaporizers.	**Result: pass**
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices FR Recognition List Number: 054 FR Recognition Number: 5-129	This standard has been used to verify and validate the usability of the QualityFlow O2 demand valve	**Result: pass**
ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices FR Recognition List Number: 053 FR Recognition Number: 5-125	This international standard has been used as a process for our medical devices for the identification and assessment of hazards and associated risks, the control of these risks and the monitoring of the effectiveness of risk control measures.	**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.	**Result: pass**

ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process FR Recognition List Number: 051 FR Recognition Number: 2-258	The standard has been used for biological evaluation of medical devices and testing within a risk management process	**Result: pass**
ISO 18562-1 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process FR Recognition List Number: 049 FR Recognition Number: 1-134	The standard has been used for Biocompatibility evaluation of breathing gas pathways in healthcare applications. Contact classification of the QualityFlow O2 demand valve: Indirect patient contact provided via medical oxygen 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: limited exposure - MEDICAL DEVICE, part or ACCESSORY whose cumulative single, multiple or repeated use does not exceed 24 hours within the scope of the standard ISO 18562-1	**Result: pass**
ISO 18562-3 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds FR Recognition List Number: 049 FR Recognition Number: 1-136	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Gas emission VOC assessment with a risk assessment of any identified chemical.	**Result: pass**

Table 3: 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 **SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE (K953349).**

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

8.12 Animal testing

No animal testing was performed.

8.13 Clinical tests

The subject of this premarket submission, QualityFlow O2 demand valve, do not require clinical studies to support substantial equivalence.

8.14 Discussion of Differences

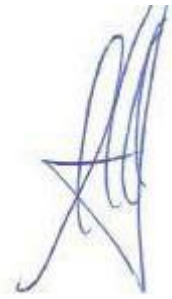
There are a few differences between the subject device and the predicate device **SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE (K953349).** The differences between the predicate and the subject device are addressed when we compare the subject device to the reference devices. The differences are outlined and discussed in the Substantial equivalence discussion.

8.15 Substantial equivalence conclusion

As outlined in the equivalence discussion, differences of the devices do not raise any questions of effectiveness and safety. Evaluation and performance tests according to the used equivalent standards show, that the subject device passed and meets the acceptance criteria and the performance is better or identical than the predicate device. We can find the subject device substantially equivalent to the predicate device SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE (K953349).

DEHAS Medical Systems GmbH considers the QualityFlow O2 demand valve to be as safe, as effective, and performance is substantially equivalent to the predicate device SPIRACLE TECHNOLOGY GASEOUS OXYGEN SUPPLY VALVE (K953349).

Submitted by:



Jens Mittendorf

Managing Director

DEHAS Medical Systems GmbH