December 7, 2022

Drägerwerk AG & Co. KGaA
Luise Lang
Regulatory Affairs Manager
Moislinger Allee 53-55
Lüebeck, Schleswig-Holstein 23542
Germany

Re: K221836
Trade/Device Name: Filter CareStar Plus, Filter SafeStar Plus, Filter/HME TwinStar Plus
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: November 4, 2022
Received: November 4, 2022

Dear Luise Lang:

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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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)*
K221836

Device Name
Filter CareStar Plus / Filter SafeStar Plus / Filter/HME TwinStar Plus

Indications for Use *(Describe)*

Filter CareStar Plus
Intended use
Bidirectionally breathing system filter against bacterial and viral contamination for anesthetic and respiratory use.

Indications
All devices are intended for single use up to 24 hours and must be used by trained medical personnel only. The devices are designed for use with ventilators and anesthesia machines.
They are intended for use in pediatric (with a tidal volume between 100 and 500 ml) and adult patients, depending on the respective device.

Filter SafeStar Plus
Intended use
Bidirectionally breathing system filter against bacterial and viral contamination for anesthetic and respiratory use.

Indications
All devices are intended for single use up to 24 hours and must be used by trained medical personnel only. The devices are designed for use with ventilators and anesthesia machines.
They are intended for use in adult patients.

Filter/HME TwinStar Plus
Intended use
Bidirectionally breathing system filter against bacterial and viral contamination for anesthetic and for respiratory use, as well as heat and moisture exchanger for humidifying respired gases for the patient.

Indications
All devices are intended for single use up to 24 hours and must be used by trained medical personnel only. The devices are designed for use with ventilators and anesthesia machines.
They are intended for use in adult, pediatric and neonatal patients, depending on the respective device.

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) Premarket Notification Summary

Submitter: Drägerwerk AG & Co. KGaA
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Establishment's registration number: 9611500

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Date prepared: December 6, 2022

Device Name:

Trade Name:	Filter CareStar Plus, Filter SafeStar Plus, Filter/HME TwinStar Plus
Classification Name:	Filter, Bacterial, Breathing Circuit
Regulation Number:	21 CFR § 868.5260
Product Code:	CAH
Class:	II

Predicate Device:

The Filter CareStar Plus is substantially equivalent to the Bact-Trap from Pharma Systems AB (K202459).

The Filter SafeStar Plus is substantially equivalent to the HepaShield Breathing System Filter from Flexicare Medical Limited (K191909)

The Filter/HME TwinStar Plus is substantially equivalent to VR Medical Heat and Moisture Exchanger Filter from VR Medical Technology Co. (K132709).

Reference Device (for Filter/HME TwinStar Plus):

EMS Electra Filter and Filter/HME (K013122)

Device Description

The devices are breathing circuit filters used to filter the inhaled and/or the exhaled air of the patient against microbiological and particulate matter from the gases in the breathing circuit. They enclose a filter material in a housing that fits to standard breathing system connectors.

Additionally, there are breathing system filters combined with a foam to function as HME (Heat and Moisture Exchangers) for passively humidifying the inspired air.

The portfolio contains the following types of breathing circuit filters:

- Filter CareStar Plus are electrostatic filters for use against contamination with microorganisms
- Filter SafeStar Plus are mechanical filters for use against contamination with microorganisms
- Filter/HME TwinStar Plus are filters for use against contamination with microorganisms and for passive humidification of breathing gases

Indications for Use

Filter CareStar Plus

Intended use

Bidirectionally breathing system filter against bacterial and viral contamination for anesthetic and respiratory use.

Indications

All devices are intended for single use up to 24 hours and must be used by trained medical personnel only. The devices are designed for use with ventilators and anesthesia machines.

They are intended for use in pediatric (with a tidal volume between 100 and 500 ml) and adult patients, depending on the respective device.

Filter SafeStar Plus:

Intended use

Bidirectionally breathing system filter against bacterial and viral contamination for anesthetic and respiratory use.

Indications

All devices are intended for single use up to 24 hours and must be used by trained medical personnel only. The devices are designed for use with ventilators and anesthesia machines.

They are intended for use in adult patients.

Filter/HME TwinStar Plus:

Intended use

Bidirectionally breathing system filter against bacterial and viral contamination for anesthetic and for respiratory use, as well as heat and moisture exchanger for humidifying respired gases for the patient.

Indications

All devices are intended for single use up to 24 hours and must be used by trained medical personnel only. The devices are designed for use with ventilators and anesthesia machines. They are intended for use in adult, pediatric and neonatal patients, depending on the respective device.

Comparison to Predicate

Filter CareStar Plus

Specification	Proposed Device	Predicate Device	Comments
	Filter CareStar Plus	**Bact-Trap**	
Manufacturer	Drägerwerk AG & Co. KGaA	Pharma Systems AB	
510(k) Number	K221836	K202459	-
Regulation Number	868.5260 Breathing circuit bacterial filter	868.5260 Breathing circuit bacterial filter	Same
Product Code	CAH	CAH	Same
Classification	Class II	Class II	Same
Intended Use/ Indications for Use	Bidirectionally breathing system filter against bacterial and viral contamination for anesthetic and respiratory use. All devices are intended for single use up to 24 hours and must be used by trained medical personnel only. The devices are designed for use with ventilators and anesthesia machines. They are intended for use in pediatric (with a tidal volume between 100 and 500 ml) and adult patients, depending on the respective device.	Bact Trap filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross contamination with microrganisms and particulate matter via anaesthetic or ventilator breathing systems. The Bact Trap filter may either be used on the patient side or on the device side of the ventilator anaesthetic device.	Similar
Patient Population	Adult and pediatric patients with a tidal volume from 100 to 1500 ml	Adult patients with a tidal volume from 50 to 1500 ml	Similar
Device configuration	Straight with luer port	-	-
Materials	Housing: Polypropylene Filter media: Polypropylene with synthetic fibers	Housing: SBC, Polypropylene, Polyethylene Filter media: Acrylic and Polypropylene fibers	Similar

Sterility	Non-sterile	Non sterile	Same
Application	Disposable up to 24 hours	Disposable up to 24 hours	Same
Biocompatibility testing	ISO 10993 and ISO 18562-1 compliant	ISO 10993 and ISO 18562-1 compliant	Same
Filtration performance	ISO 23328-1 compliant and ASTM F2101 compliant	ISO 23328-1 and ASTM F2101 compliant	Same
Compliance, leakage and pressure drop	ISO 23328-2 and ISO 9360-1 compliant	ISO 23328-2 and ISO 9360-1 compliant	Same
Technological Characteristics			
Principle of Operation	Electrostatic filtration method	Electrostatic filtration method	Same

Specification	Proposed Device	Predicate Device	Comments
	Filter CareStar Plus	**Bact-Trap**	
Connectors	Standard conical connectors Luer lock port for gas sampling	Standard conical connectors Luer lock port for gas sampling	Same
General Performance			
Resistance	@30 l/min: ≤ 1.3 mbar	@30 l/min: = 1.1 mbar	Similar
Filtration efficiency	BFE: ≥ 99,99% VFE: ≥ 99,9 %	BFE: > 99,999 % VFE: > 99,99 %	Similar
Shelf-Life	3 years	3 years	Same
Dead Space	20 to 35 ml	23 to 76 ml	Similar
Leakage at 70 mbar	≤ 15 ml / min	Not stated	-
Compliance	≤ 1 ml / kPa	Not stated	-

Filter SafeStar Plus

Specification	Proposed Device	Predicate Device	Comments
	Filter SafeStar Plus	**HepaShield Breathing System Filter**	
Manufacturer	Drägerwerk AG & Co. KGaA	Flexicare Medical Limited	
510(k) Number	K221836	K191909	-
Regulation Number	868.5260 Breathing circuit bacterial filter	868.5260 Breathing circuit bacterial filter	Same
Product Code	CAH	CAH	Same
Classification	Class II	Class II	Same
Intended Use / Indications for Use	Bidirectionally breathing system filter against bacterial and viral contamination for anesthetic and respiratory use. All devices are intended for single use up to 24 hours and must be used by trained medical personnel only. The devices are designed for use with ventilators and anesthesia machines. They are intended for use in adult patients.	Flexicare's HepaShield Bacterial Viral Breathing System Filters are intended to reduce the transmission of bacteria and viruses to/from a patient during anesthesia. For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired. Flexicare's HepaShield Bacterial Viral Breathing System Filters are single use devices for use on a single patient for up to 24hrs and are available in adult size. Flexicare's HepaShield Bacterial Viral Breathing System Filters are designed to be used in hospital environments by trained personnel.	Similar
Patient Population	Adult patients with a tidal volume from 100 to 1500 ml	Adult patients with a tidal volume of 141 to 800 ml	Similar
Device configuration	Straight and angular versions with luer port	Straight with luer port	Similar

Materials	Housing: Polypropylene Filter media: Paper with glass fibers Casting compound: Polyolefin	Unknown	-
Sterility	Non-sterile	Sterile and no-sterile variants	similar
Application	Disposable Up to 24h	Disposable Up to 24h	Same
Biocompatibility testing	ISO 10993 and ISO 18562-1 compliant	ISO 10993 and ISO 18562-1 compliant	Same
Filtration performance	ISO 23328-1 compliant and ASTM F2101 compliant	ISO 23328-1 compliant and ASTM F2101 compliant	Same
Compliance, Leakage and pressure drop	ISO 23328-2 and ISO 9360-1 compliant	ISO 23328-2 and ISO 9360-1 compliant	Same
Technological Characteristics			
Principle of Operation	Mechanical filtration method	Mechanical filtration method	Same

Specification	Proposed Device	Predicate Device	Comments
	Filter SafeStar Plus	**HepaShield Breathing System Filter**	
Connectors	Standard conical connectors Luer lock port for gas sampling	Standard conical connectors Luer lock port for gas sampling	Same
General Performance			
Resistance	@30 l/min: ≤ 2 mbar	@30 l/min: = 1.7 mbar	Similar
Filtration efficiency	BFE: ≥ 99,999 % VFE: ≥ 99,999 %	BFE: 99,99999 % VFE: 99,9999 %	Similar
Shelf-Life	5 years	5 years	Same
Dead Space	55 to 90 ml	47 ml	Different
Leakage at 70 mbar	≤ 15 ml / min	< 2ml / min	Different
Compliance	≤ 1 ml / kPa	0.057 ml / cmH2O	Similar

Filter/HME TwinStar Plus

Specification	Proposed Device	Predicate Device	Reference Device	Comments
	Filter/HME TwinStar Plus	**VR Medical Heat and Moisture Exchanger Filter**	**EMS Electra Filter and Filter/HME**	
Manufacturer	Drägerwerk AG & Co. KGaA	VR Medical Technology Co.	Engineered Medical Systems, Inc.	
510(k) Number	K221836	K132709	K013122	-
Regulation Number	868.5260 Breathing circuit bacterial filter	868.5260 Breathing circuit bacterial filter	868.5260 Breathing circuit bacterial filter	Same
Product Code	CAH	CAH	CAH	Same
Classification	Class II	Class II	Class II	Same
Intended Use / Indications for Use	Bidirectionally breathing system filter against bacterial and viral contamination for anesthetic and for respiratory use, as well as heat and moisture exchanger for humidifying respired gases for the patient. All devices are intended for single use up to 24 hours and must be used by trained medical personnel only. The devices are designed for use with ventilators and anesthesia machines. They are intended for use in adult, pediatric and neonatal patients, depending on the respective device.	The Heat and Moisture Exchanger and Filter is a disposable single-use device indicated for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross contamination between patient and equipment. The products mentioned above are designed for disposable use and should be changed at least every 24 hours	For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired and to add maintain and retain moisture for the exhaled breathe of the patient	Similar

Specification	Proposed Device	Predicate Device	Reference Device	Comments
	Filter/HME TwinStar Plus	**VR Medical Heat and Moisture Exchanger Filter**	**EMS Electra Filter and Filter/HME**	
Patient Population	Neonatal, pediatric, and adult patients with a tidal volume from 30 to 1500 ml.	Adult patients with a tidal volume from 250 to 1500 ml	Neonatal, pediatric and adult patients with a tidal volume from 20 cc to > 150 cc.	Similar
Device configuration	Straight and angular versions with luer port	-	-	-
Materials	Housing: Polypropylene Filter media: Polypropylene with synthetic fibers (except Filter/HME TwinStar HEPA Plus, which uses paper with glass fibers) HME-Media: Polyurethane impregnated with calcium chloride	Housing: K-Resine Filter media: Polyolefin synthetic fibers (except VR005 which uses paper with glass fibers) HME-Media: Polyurethane impregnated with calcium chloride	Housing: Polystyrene Filter media: Electrostatic polypropylene	Different
Sterility	Non-sterile	Non-sterile	Unknown	Same

Application	Disposable up to 24 hours	Disposable up to 24 hours	Disposable up to 24 hours	Same
Biocompatibility testing	ISO 10993 and ISO 18562-1 compliant	ISO 10993 compliant	Unknown	Similar
Filtration performance	ISO 23328-1 compliant and ASTM F2101 compliant	ISO 23328-1 compliant	Unknown	Similar
Compliance, Leakage and pressure drop	ISO 23328-2 and ISO 9360-1 compliant	Unknown	Unknown	-
Technological Characteristics				
Principle of Operation	Electrostatic or mechanical filtration method combined with a foam for passive humidification	Electrostatic or mechanical filtration method combined with a foam for passive humidification	Electrostatic filtration method combined with a foam for passive humidification	Same

Connectors	Standard conical connectors Luer lock port for gas sampling	Standard conical connectors Luer lock port for gas sampling	Standard conical connectors Luer lock port for gas sampling	Same
General Performance				
Resistance				
Adult	@30 l/min: ≤ 1.6 mbar	@30 l/min: ≤ 1.5 mbar	@30 l/min: not stated	Similar
Neonatal / Pediatric	@15 l/min: ≤ 1.5 mbar	-	@20 l/min: 1.0 cmH2O	
Filtration efficiency				
BFE VFE	≥ 99,98 % ≥ 99,9 %	99.999 % 99.99%	≥ 99.999 % ≥ 99.99 %	Similar

Moisture loss / Moisture return[1]				
Adult	Moisture loss @ Vt= 500 ml ≤ 10.9 mg/l (which results in a moisture return of ≥ 33,1 mg/l)	Moisture loss @ Vt = 500 ml: ≤ 10.5 mg/l	Moisture return @ Vt = 1000 cc: = 32 mg/l	Similar
Pediatric	Moisture loss @ Vt = 250 ml: ≤ 11.8 mg/l (which results in a moisture return of ≥ 32,2 mg/l)	-	Moisture return@ Vt = 250 cc: = 32 mg/l	Similar
Neonatal	Moisture loss @ Vt=50ml: ≤ 10.3 mg/l (which results in a moisture return of ≥ 33.7 mg/l)	-	Moisture return @ Vt= 50 ml: = 30 mg/l	Similar
Shelf-Life	3 or 5 years, depending on the respective device	Not stated	Not stated	-
Dead space	9 to 90 ml	60 to 85 ml	10 to 65 ml	Similar
Leakage at 70 mbar	≤ 15ml / min	-	-	-
Compliance	≤ 1ml / kPa	-	-	-

[1] Moisture return = 44 mg/l – moisture loss

Discussion of Non-clinical Testing

The devices Filter CareStar Plus, Filter SafeStar Plus and Filter/HME TwinStar Plus are new products and have undergone extensive testing to qualify it with e.g. national and international consensus standards, technical system requirements and other requirements. The following identified verification and validation activities necessary to establish substantial equivalence to the predicate device were carried out and well-established method, the evidence is included in this 510(k) submission.

- Biocompatibility
- Technical system requirements, including
  - Technical data
  - Essential safety and performance
- Connectors
- Human factors engineering

Summary of non-clinical testing

Test method	Purpose	Acceptance criteria	Result
ISO 9360-1:2000	Determination and Evaluation of Pneumatic Compliance	compliance is less than or equal to 1mL/kPa at 15, 30, 60, and 70 hPa	PASSED
ISO 9360-1:2000	Determination and Evaluation of Pneumatic Leakage	pneumatic leakage is less than or equal to 50mL/min at 70hPa.	PASSED
ISO 9360-1:2000	Determination and Evaluation of Pressure Drop (Pneumatic Resistance)	pneumatic resistance/pressure drop is acc. to IfU value	PASSED
ISO 5356-1:2015	Evaluation of Conical Connectors (ISO 5356-1)	cone dimensions comply with ISO 5356-1.	PASSED
ISO 80369-7:2021	Luer Lock Connector (ISO 80369-7)	Luer-Lock connector fulfills the requirements laid out in ISO 80369-7.	PASSED
IEC 60601-1:2005	Product's Ability to Withstand Damage from Dropping	When dropped, the product should not suffer any damage which influences its function.	PASSED

ISTA 3A	Product Durability During Transport, Mechanical Aspects	- the packaging shows no or minor damage - the DUT shows no signs of damage and retains functionality after simulated transport.	PASSED
ISO 23328-1:2003	Filtration Efficiency (Particulate Matter) incl. Usage Time	- adult and pediatric electrostatic filters achieve a filtration efficiency of >90% before and after the specified usage time - neonatal filters achieve a filtration efficiency of >75% before and after the specified usage time - mechanical filters achieve a filtration efficiency of >99% before and after the specified usage time - mechanical filters achieve a HEPA classification ≥ class H13	PASSED
ASTM F2101:2019	Filtration Efficiency (Viral and Bacterial)	- electrostatic filters achieve 99.99% (bacterial) and 99.9% (viral) filtration efficiency - electrostatic filters for neo applications achieve 99.98% (bacterial) and 99.9% (viral) filtration efficiency.	PASSED
ISO 10993:2018 and ISO 18562-1:2017	Evaluation of Product's Biological Compatibility (ISO 10993:2018 and ISO 18562-1:2017)	evaluation according to ISO 10993:2018 and/or ISO 18562-1:2017	PASSED
ISO 9360-1:2000	Evaluation of HME Water Loss, Resistance	·pediatric/neonatal: The moisture loss shall be <=11mg/L at VT=50ml ·pediatric: The moisture loss shall be <=12mg/L at VT=250ml · adult: The moisture loss shall be <=11mg/L at VT=500ml	PASSED

List of Consensus Standards

Standard Number and Version	Title
AAMI ANSI ISO 5356-1:2004	Anaesthetic And Respiratory Equipment – Conical Connectors: Part 1: Cones And Sockets
ISO 18652-1:2017	Biocompatibility Evaluation Of Breathing Gas Pathways In Healthcare Applications
AAMI / ANSI / IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
ANSI AAMI ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ASTM F2101-19:2019	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials
EN ISO 9360-1:2009	Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml
EN ISO 23328-1:2008	Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance
EN ISO 23328-2:2009	Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects

Summary of Clinical Testing

N/A.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Filter CareStar Plus, Filter SafeStar Plus and Filter/HME TwinStar Plus are as safe, as effective and perform as well as or better than the legally marketed devices identified in this section.

- END -