510(k) Summary

K072002

Summary of Safety and Effectiveness

JAN 31 2008

Applicants Name and Address:

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Contact Person:

Dr. Karin Luebbers
Senior Manager Regulatory Affairs

Tel. No.: + 49 (451) 882-5367
Fax No.: + 49 (451) 882-7-5367

Applicants US Contact Person

Ms. Kathy Anderson
Sr. Director Regulatory Affairs

Tel. No.: (215) 660-2078
Fax No.: (215) 721-5424

Date submission was prepared:

2007-07-13

Device Name:

Trade Name:	Filter CareStar 30
Common Name:	Breathing circuit bacterial filter
Trade Name:	Filter SafeStar 55
Common Name:	Breathing circuit bacterial filter
Trade Name:	Filter/HME TwinStar 55
Common Name:	Breathing circuit bacterial filter

015

Classification:

Regulation No.	Device	Product Code
868.5260	Breathing circuit bacterial filter	(73CAH)
868.5375	Heat and moisture condenser (artificial nose)	(73BYD)

Legally Marketed Device to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K031653	Datex-Ohmeda HMEF 750	Datex-Ohmeda
K033008	Air Safety HEPA and non-HEPA Filters	AirSafety
K030990	Datex-Ohmeda Mini-Filter/S Datex-Ohmeda Uni-Filter Junior	Datex-Ohmeda
K014282	Bacstop, Bacstop mini, Bacstop Humini	Munktell
K013089	EMS HEPA Filter	EMS

Device Description:

The filters CareStar 30 and SafeStar 55 are designed to reduce possible air or liquid borne cross contamination with microorganisms via anesthetic or ventilator breathing systems. The strategic use of an effective breathing filter protects, bi-directionally, both the patient and equipment.

The filter CareStar 30 contains an electrostatic filter pad while the filter SafeStar 55 incorporates a mechanical pleated filter pad. Both filters consist of a plastic body which incorporates 22 female / 15 male connectors in accordance with EN ISO 5326 and a luer lock connector which may only be used for gas monitoring.

The Filter/HME TwinStar 55 is designed to combine the feature of reducing possible cross contamination with micro-organisms and an ideal heat and moisture return.

The Filter/HME TwinStar 55 consist of a plastic body which incorporates an electrostatic filter pad, 22 female / 15 male connectors in accordance with EN ISO 5326 and a gas luer lock connector which may only be used for gas monitoring.

	Filter CareStar 30 MP01770	Filter SafeStar 55 MP01790	Filter / HME TwinStar 55 MP01805
Filtration efficiency (by *Nelson Lab.*)	99.999% (BFE*) 99.99% (VFE*)	99.9999% (BFE*) 99.9999% (VFE*)	99.999 % (BFE*) 99.99 % (VFE*)
Filtration mechanism	electrostatic	mechanical	electrostatic
Resistance to flow	(0.7 cmH_2O at 30 L/min)	(1.4 cmH_2O at 30 L/min)	(0.7 cmH_2O at 30 L/min)
Internal volume	30 mL	55 mL	55 mL

	Filter CareStar 90 MP01770	Filter SafeStar 55 MP01790	Filter/HME SafeStar 55 MP01790
Recommended tidal volume	100 to 1500 mL	200 to 1500 mL	200 to 1500 mL
Conical connectors *ISO 5356*	22m/15f – 22f/15m	22m/15f – 22f/15m	22m/15f – 22f/15m
moisture loss ISO 9360	No	No	7,1 mg/L at VT = 500 mL
Gas sampling port	Yes	Yes	Yes
Materials:			
Housing:	PP	PP	PP
Filter medium	PP with synth. fibres	Paper with glass fibre	Paper with glass fibre

BFE: Bacterial filtration efficiency
VFE: Virus filtration efficiency

Intended Use:

Product	Intended use:
Filter/HME TwinStar	Breathing system filters for anesthetic and respiratory use and heat and moisture exchangers (HMEs) for humidifying respired gases in humans
Filter CareStar	Breathing system filters for anesthetic and respiratory use
Filter SafeStar	Breathing system filters for anesthetic and respiratory use

Substantial Equivalence:

The intended use of the breathing circuit filters is comparable to the referenced predicate devices.

The comparison of the data shows similar values for the key performance data. Proposed devices show similar values in filtration efficiency, dead space, resistance to flow and recommended tidal volumes when compared to the legally marketed devices.

It must be pointed out that there is an interdependency regarding filtration efficiency, moisture loss, dead space and resistance to flow. A higher amount of media will result in a higher efficiency in filtration or humidification but with the consequence of having more dead space and higher resistance to flow.

In summary Dräger Medical AG & Co. KG has demonstrated that the proposed devices are safe and effective. They are considered to be substantially equivalent to currently marketed predicate devices which have been previously cleared by the FDA.

017

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

Draeger Medical AG & Company KG
C/O Ms. Kathy Anderson
Senior Director Regulatory Affairs
Draeger Medical System, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K072002
Trade/Device Name: Breathing System Filter CareStar 30, Breathing System Filter SafeStar 55, Breathing System Filter /Heat and Moisture Exchanger TwinStar 55
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: January 25, 2008
Received: January 28, 2008

Dear Ms. Anderson:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072002

Device Name: Breathing System Filter CareStar 30,
Breathing System Filter SafeStar 55,
Breathing System Filter / Heat and Moisture Exchanger TwinStar 55

Indications for Use:

CareStar 30 and SafeStar 55 are Breathing System Filters which are designed to reduce possible airborne or liquid-borne cross contamination with micro-organisms and particulate matter via anaesthetic or ventilator breathing systems.
The products may either be used on the patient side or on the device side of the ventilator/ anaesthetic device and are used as a hygienic measure alternatively to decontamination of breathing system and/or breathing gas conveying parts of the ventilator.

TwinStar 55 is a Breathing System Filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchanger are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The products are the only conditioning opportunity of breathing gases in cases of emergency ventilation or during transport since Heated Humidifiers are almost impossible to use.

The products mentioned above are designed for disposable use and should be changed at least every 24 hours.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072002