K132709

JUL 30 2014

SECTION 5 510(k) SUMMARY

Date of Submission: August 16, 2013

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Proprietary Name: VR Medical Heat and Moisture Exchanger and Filter

Common/ Usual Name: Breathing Circuit Bacterial Filter

Classification Reference: 21 CFR 868.5260

Product Code: CAH

Predicate Devices: Datex- Ohmeda HMEF 750 (K031653)
Datex- Ohmeda HMEF Mini (K023641)
Drager Medical Breathing Circuit Bacterial Filter (K072002)
Engineering Medical Systems HEPA Filter / HME (K013089)

Indication for Use:
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.

Patient Population/ Environment of Use:
The Heat and Moisture Exchanger and Filter is for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The device can be used on adult patients. The device is indicated for use by qualified medical personnel only.

Device Description:
The Heat and Moisture Exchanger and Filter (HMEF) consists of a plastic body which incorporates an electrostatic/ mechanical filter pad, 22 mm female / 15 mm male connectors in accordance with ISO 5356 (Anaesthetic and respiratory equipment-Conical connectors- Part 1: Cones and sockets) and a luer lock connector which is only used for gas monitoring.

Item	HMEF VR003	HMEF VR005
Filtration efficiency (By Nelson Lab)	99.999% (BFE*) 99.99% (VFE*)	99.9999% (BFE*) 99.999% (VFE*)
Filtration mechanism	electrostatic	mechanical
Pressure Drop	0.7 cm H2O at 30 L/min	1.5 cm H_20 at 30 L/min
Internal Volume	60mL	85mL
Recommended tidal volume	250 to 1500 mL	250 to 1500 mL
Conical connectors ISO 5356	15 mm Inner Diameter (ID) X22 mm Outer Diameter (OD) fitting to connect to the endotracheal tube or face mask 15 mm OD X22 mm ID fitting to connect to the breathing circuit Y-piece	15 mmiDX22 mm OD fitting to connect to the endotracheal tube or face mask 15 mm OD .fitting to connect to the breathing circuitY-piece
Moisture loss ISO 9360*	10.5 mg/L at VT=500 mL	7.8 mg/L at VT=500 mL
Gas sampling port	Yes	Yes
Material		
Housing:	K-Resin (Styrene- Butadiene Copolymer Plastic)	K-Resin (Styrene-Butadiene Copolymer Plastic)
Filter medium	Synthetic fibers (Polyolefin)	Paper glass fiber
Foam	, Polyurethane (PU) impregnated with calcium chloride (CaC12)	Polyurethane (PU) impregnated with calcium chloride (CaC12)

*Notes
BFE: Bacterial filtration efficiency
VFE: Virus filtration efficiency
ISO 9360: 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

Design verification tests (as well as an evaluation under ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process) were conducted on the HMEF as a result of the resulting risk analysis and product requirements.

It must be noted that the HMEF is provided non-sterile. Therefore, all corresponding sterilization tests are not necessary and were not performed.

Substantial Equivalence:

The intended use and indications for use for the proposed device are the same as the predicate devices.

The comparison of the data demonstrates similar values for the key performance data. The VRM HMEF devices demonstrate similar values in filtration efficiency, internal volume, pressure drop 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, internal volume and pressure drop. A higher amount of media will result in a higher efficiency in filtration or humidification but with the consequence of having more internal volume and higher pressure drop.

The main differences that may influence the technological characteristics between the proposed device and the predicate devices are the different shape and size of the housing. The shape of the proposed device is cuboid-shaped, but the predicate devices are cylinder-shaped. These differences can influence the performance of internal volume and related performances, but as the designed volume of the housing is substantial equivalent to predicate devices, the proposed device have the similar internal volume and related performances as the predicated devices. Thus the differences between the subject device and the predicate devices do not raise new questions of safety and effectiveness. .

The Heat and Moisture Exchanger and Filter is manufactured from K-Resin (Styrene-Butadiene Copolymer Plastic), Polyurethane (PU), Synthetic fibers (Polyolefin), Paper glass fibers. All materials have been evaluated in accordance with ISO 10993-1 Biological Evaluation of Medical Device -Part 1: Evaluation and testing within a risk management process and FDA General Program Memorandum #G95-1. Thus, VR Medical conducted two confirmatory in-vitro tests (utilize both polar and non-polar solvents) and five confirmatory tests (cytotoxicity, sensitization, irritation, genotoxicity, and implantation) which confirmed the acceptable biocompatible status of these materials.

Summary of Non-Clinical Tests:

The following in-vitro tests were conducted:

- Bacterial Filtration Efficiency (BFE)
- Viral Filtration Efficiency (VFE)
- Salt Test (ISO 23328-1)
- Pressure Drop
- Internal Volume
- Moisture Loss
- Conical Connectors Related Performance (ISO 5356)
  (Including the General Requirements and Special Requirement)

- Package Integrity
- Accelerated Aging

Package Transport Test**

- Constant Temperature and Humidity
- Compression Testing
- Fixed Displacement Vibration Testing
- Free Fall Drop Testing

** Package Transport Test Standards Utilized

ISTA-2A ISTA Packaged Products 150 lb (68 kg) or less; ISTA 2 Series Partial Simulation Performance Test Procedure

ASTM D4169-08 Standard Practices for Performing Testing of Shipping Containers and Systems

Biocompatibility

- According to evaluation using ISO 10993-1 and FDA 095-1;
- The materials are either identical to, or substantially equivalent to predicate devices;
- Furthermore, two confirmatory in-vitro tests (utilize both polar and non-polar solvents) and five confirmatory tests (cytotoxicity, sensitization, irritation, genotoxicity, and implantation) demonstrated the materials acceptable biocompatible status
  - Cytotoxicity (ISO 10993-5:2009)
  - Sensitization (ISO 10993-10:2010)
  - Irritation (ISO 10993-10:2010)
  - Genotoxity (ISO 10993-3:2003)
  - Implantation (ISO 10993-6:2007)

Summary of Clinical Tests:

The subject of this premarket submission, VR Medical Heat and Moisture Exchanger and Filter did not require clinical studies to support substantial equivalence.

Conclusion

VR Medical has demonstrated that the proposed device is as safe, as effective and the performance testing results are substantially equivalent to the described predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2014

VR Medical Technology Co.
Lee Pan, Ph.D.
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Kun Shan, Jiangsu 215325
CHINA

Re: K132709

Trade/Device Name: VR Medical Heat and Moisture Exchanger and Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Class: II
Product Code: CAH
Dated: May 21, 2014
Received: June 30, 2014

Dear Dr. Pan:

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
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Radiological Health

Enclosure

SECTION 4 INDICATION FOR USE STATEMENT

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510(k) Number (if known): K132709

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

K132709

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