



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medisize B V
C/O Mr Harry J van Vugt
Responsible Third Party Official
KEMA Quality B V
4377 County Line Road
Chalfont, Pennsylvania 18914

JAN 23 2009

Re K081536
Trade/Device Name Bacterial/Viral Medizize Blue and Medisize Red Filters
Regulation Number 21 CFR 868 5260
Regulation Name Breathing Circuit Bacterial Filter
Regulatory Class II
Product Code CAH
Dated January 8, 2009
Received January 9, 2009

Dear Mr van Vugt

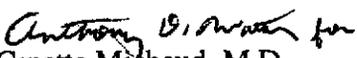
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,


Ginette Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Section #3 -
INDICATIONS FOR USE**

510(k) Number (if known): k081536

Device Name Bacterial/Viral filter and HME combination device

Product numbers. See table below

| Device name | Catalogue code |
|-----------------------------------|----------------|
| Medisize Blue Big HMEF | 303 100 000 |
| Medisize Blue Small HMEF | 303 200 000 |
| Medisize Blue S-Angled HMEF | 303 210 000 |
| Medisize Blue HMEF Child Straight | 303 520 000 |
| Medisize Blue HMEF Child Angled | 303 610 000 |
| Medisize Red Big Filter | 303 300 000 |
| Medisize Red Small Filter | 303 400 000 |
| Medisize Red Angled Filter | 303 410 000 |

Indications for Use:

- 1 The Medisize Red devices are breathing circuit bacterial filters, which are intended to remove microbiological and particulate matter from the gases in the breathing circuit
- 2 The Medisize Blue devices are Filter/HME's. These devices are intended to remove microbiological and particulate matter from the gases in the breathing circuit and at the same time the device is intended to be positioned over a tracheotomy or tracheal tube to warm and humidify by passive means gases breathed in by patient during anaesthesia and ventilator care

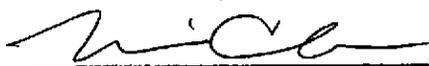
Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)



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

510(k) Number K081536

 - Quality Manager
08 January 2004