K122885

Section 5 – 510(k) Summary for Medisize Gold Heater and Booster T-Piece

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

29 August 2013

4. Device Name

Trade/Proprietary Name: Medisize Gold Heater and Booster T-Piece
Common/Usual Name: Respiratory gas humidifier
Classification Name: Respiratory Gas Humidifier
Classification Regulation: 21 CFR 868.5450
Classification Panel: Anesthesiology
Product Code: BTT
Device Class: Class II

FDA Establishment Registration #: 3002598726

5. Predicate Devices

MEDISIZE GOLD Heater and Booster manufactured by Medisize B.V., 510(k) number: K070714

6. Device Description

The reusable MEDISIZE GOLD Heater in combination with the disposable single use Medisize Gold Booster T-Piece (or Medisize Gold, 510k number K052615) combines the simplicity of a Heat and Moisture Exchanger (HME) with the features of active humidification. Use of the MEDISIZE GOLD Heater in combination with a HME increases the number of options for humidifying and heating respiratory gases, greatly expanding the field of application for HMEs. When used in combination with a HME, the MEDISIZE GOLD Heater improves the absolute humidity, the relative humidity and the temperature of the respiratory gases. Use of the MEDISIZE GOLD Heater makes it possible to administer additional moisture and heat in a simple way, which is self-regulating. As a result, use of the MEDISIZE GOLD Heater is not particularly labor or knowledge intensive. The ease of use makes it a reliable, stable and effective method to administer additional moisture and heat to patients when required.

7. Intended Use

The MEDISIZE GOLD Heater and Booster T-Piece is intended to feed additional heat and moisture into the system, through the T-Piece or via the Medisize Gold, during anaesthesia and respiratory care, specifically, when the use of an HME alone is no longer adequate due to the patients moisture deficit.

8. Technological Characteristics and Substantial Equivalence

The following table compares the predicate Medisize Gold Heater and Booster (with T-Piece) to the modified Medisize Gold Heater and Booster T-Piece with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5-A: Device Comparison Table

Manufacturer	**Medisize B.V.**	**Medisize B.V.**
Trade Name	Medisize Gold Heater and Booster T-Piece	Medisize Gold Heater and Booster (with T-Piece) (Predicate device)
510(k) Number	K122885	K070714
Product Code	BTT	BTT
Regulation Number	21 CFR 868.5450	21 CFR 868.5450
Regulation Name	RESPIRATORY GAS HUMIDIFIER	RESPIRATORY GAS HUMIDIFIER
Indications for use:	Feeds additional heat and moisture into the respiratory system when the use of a HME alone is not adequate.	Feeds additional heat and moisture into the respiratory system when the use of a HME alone is not adequate.
Overall Design	Re-usable heater used with single use disposable component in gas stream	Re-usable heater used with single use disposable component in gas stream
Mode of Operation	Can administer heat and humidity to anaesthesia gas stream at temperature of approximately 33°C, 33 mg/L	Can administer heat and humidity to anaesthesia gas stream at temperature of approximately 33°C, 33 mg/L
Complies with IEC 60601-1	Yes	Yes
Complies with IEC 60601-1-2	Yes	Yes
Power Supply	FW7660M/09 Input:100-240V~/50-60Hz/250mA Output: 9V ---/1,0A	FW7555M/12 Input:100-240~/50-60Hz/400mA Output: 12V --- /1,25A
Operating Conditions	See Power Supply	See Power Supply
Input Cable	See Power Supply	See Power Supply
Input Cable Adapter	See Power Supply	See Power Supply

9. Non-Clinical Testing

The device has been tested for electrical safety according to IEC 60601-1 and IEC 60601-1-2 and passed all the testing. Details of the specific performance standards used are listed below and test results summarized in Table 1:

Table 5-B: Summary of Non-Clinical Test Results

Standard	Standard Title	Test Results
IEC 60601-1:2005	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance	Passed
IEC 60601-1-2:2007	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests	Passed

The device was tested for the performance testing according to the voluntary standard ISO 8185, *Respiratory Tract Humidifiers for Medical Use – Particular requirements for respiratory humidification systems*. The testing supports the acceptable results of the device according to ISO 8185 requirements.

No biocompatibility testing was performed on the Medisize Gold Heater and Booster T-Piece as part of this submission because the materials are identical to the Medisize Gold Heater and Booster (with T-Piece) cleared under the previous 510(k) clearances K070714 and K052615.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing. The verification and validation testing of the device electrical safety and EMC testing of the device was found to be acceptable and supports the claims of substantial equivalence.

11. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The modified Medisize Gold Heater and Booster T-Piece, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.

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

August 29, 2013

Medisize BV
C/O Mr. Richard Vincins
Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K122885
Trade/Device Name: Medisize Gold Heater and Booster T-Piece
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: August 7, 2013
Received: August 8, 2013

Dear Mr. Vincins:

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,

Kwame O. Ulmer
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Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122885

Section 4 - Indications for Use Statement

510(k) Number (if known): Not known

Device Name: MEDISIZE GOLD Heater and Booster T-Piece

Indications for Use:

The MEDISIZE GOLD Heater and Booster T-Piece is intended to feed additional heat and moisture into the system, through the T-Piece or via the Medisize Gold, during anaesthesia and respiratory care, specifically, when the use of an HME alone is no longer adequate due to the patients moisture deficit.

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

Anya C. Harry

Digitally signed by Anya C. Harry
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry, 0.9.2342.19200300.100.1.1=0011315590
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