

APR 19 2000

K993268

1. SPONSOR/APPLICANT NAME, ADDRESS, TELEPHONE NUMBER

MALLINCKRODT DAR S.R.L.
via G. Bove, 2/4/6/8
I-41037 Mirandola, (MODENA), ITALY

Contact Person: Giuseppe Tomasini
Telephone: 011 39 0535 617922
(E-mail: giuseppe.tomasini@mkg.com.)

Date of Summary Preparation: April 13, 2000

2. DEVICE NAME

Proprietary Name: MALLINCKRODT DAR Heated Wire Breathing Circuit
Common/Usual Name: Heated Breathing Circuits
Classification Name: Accessory to Breathing System Heater or Respiratory Gas Humidifier

3. IDENTIFICATION OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) TO WHICH EQUIVALENCE IS BEING CLAIMED

MALLINCKRODT DAR Airway Connectors with Flex Tube (K943292)
Marquest Heating Wire Breathing Circuit and Limbs (K962220)
Fisher & Paykel (K983112)

4. DEVICE DESCRIPTION

The MALLINCKRODT DAR Heated Wire Breathing Circuit consists of the existing smooth bore breathing circuits (K942392, Airway Connectors with Flex Tube) into which a resistor has been molded into the inside of the external rib. Heating is controlled by ventilation/anesthesia breathing heaters or heater/humidifiers to which the MALLINCKRODT DAR Heated Wire Breathing Circuits are electrically connected. Some HWBC configurations may include traps for collection of the condensed moisture from patient exhalation or from humidification. Devices will be available in a variety of configurations.

5. INTENDED USE

The MALLINCKRODT DAR Heated Wire Breathing Circuit is intended to warm breathing gases for adults, children, and infants undergoing anesthesia or mechanical ventilation within a health care facility.

6. A STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE

**DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED
DEVICE(S) CITED**

MALLINCKRODT DAR S.R.L. makes the claim of substantial equivalence based on intended use, design, operational characteristics, and materials of construction. A side-by-side comparison of the MALLINCKRODT DAR Heated Wire Breathing Circuits to the systems cited is provided in Table 1 below.

Table 1. Comparison of the HWBC with Predicate Devices

		MALLINCKRODT HWBC	MALLINCKRODT Airway Connectors with Flex Tube	MARQUEST	Fisher & Paykel
510(k) number		N/A	K942392	K962220	K983112
Use	Provides heated gas pathway to the ventilation circuitry	YES	NO	YES	YES
	Used for anesthesia	YES	YES	YES	YES
	Used for respiratory therapy	YES	YES	YES	YES
	Used for heated humidifiers	YES	NO	YES	YES
	Compatible with multiple humidifiers	YES	NO	NO	NO
	Indicated for single patient use	YES	YES	YES	YES
	Reprocessing/re-use contraindicated	YES	YES	NS*	NS*
Sterility	Sterile	YES	YES	NS*	NS*
	Non sterile	YES	YES	NS*	NS*
Design	Available in adult (A), pediatric (P), and neonatal (N) sizes	A, P, N	A, P, N	A	NS*
	Smooth bore	YES	YES	NS*	NS*
	Corrugated or reinforced	YES	YES	NS*	NS*
	Transparent	YES	YES	NS*	NS*
	Standard airway connectors	YES	YES	YES	YES
	Circuits with various components	YES	YES	YES	YES
	Heating wire	Encased	None	Free	Free
	Available as the Heated Single tube with connectors	YES	Not Applicable	NS*	NS*
Materials	Same materials as standard breathing circuits	YES	YES	YES	YES
Performance	Meets ASTM standards	YES	YES	YES	NS*

**Not specified*

7. TESTING

Biocompatibility, performance, electrical safety, and electromagnetic compatibility testing demonstrate that Mallinckrodt DAR HWBC comply with designated voluntary standards and fulfill product specifications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2000

Mr. Giuseppe Tomasini
Mallinckrodt DAR S.R.L.
Via G. Bove 2/4/6/8
41037 Mirandola, Modena
ITALY

Re: K993268
Mallinckrodt DAR S.R.L. Heated Wire Breathing Circuit (HWBC)
Regulatory Class: I (one), II (two)
Product Code: BTT, CAI
Dated: January 19, 2000
Received: January 20, 2000

Dear Mr. Tomasini:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

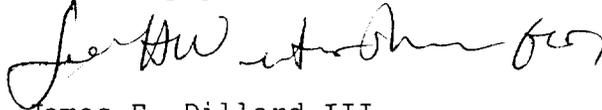
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993268

Device Name: MALLINCKRODT DAR Heated Wire Breathing Circuit

Indications for Use:

The MALLINCKRODT DAR Heated Wire Breathing Circuit is intended to warm breathing gases for adults, children, and infants undergoing anesthesia or mechanical ventilation within a health care facility.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

510(k) SUMMARY
MALLINCKRODT DAR HEATED WIRE BREATHING CIRCUIT
(PER 21 CFR 807.92)