K100941

Dräger medical
A Dräger and Siemens Company

510(k) Summary acc. to 21 CFR 807.92

Applicants Name and Address:

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

APR 23 2010

Manufacturer Name and Address:

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

Establishment Registration Number :

9611500

Contact Person:

Ulrich Schroeder
Director Regulatory & Clinical Affairs

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Applicants US Contact Person

Joyce Kilroy
Vice President, Processes, Quality & Regulatory

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Date submission was prepared:

2010-03-30

Device Name:

Common Name:	Infinity MCable - Mainstream CO_2
Classification Name:	Carbon dioxide gas analyzer, CCK
Regulation Number:	21 CFR 868.1400
Class:	II

Legally Marketed Predicate Device to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K 051263	Evita XL, Option SmartCare with Option Capno Package CO_2 Mainstream sensor #6871500	Dräger Medical AG & Co. KG
K 042601	CAPNOSTAT 5	RESPIRONICS NOVAMETRIX, INC.

Device Description:

The Infinity MCable – Mainstream CO_2 uses infrared absorption technology to accomplish mainstream CO_2 measurements. The sensor is able to measure end-tidal CO_2 and inspired CO_2 and calculates the respiratory rate. This measurement module is integrated inside the sensor and no longer part of the host device (e.g. ventilator). CO_2 compensation has been advanced for the foreign gases helium and nitrous oxide.

Technological Characteristics

The Infinity MCable – Mainstream CO_2 is based on the same technological principles as the Dräger predicate (specific dual wavelength infrared absorption by CO_2 molecules) using the same wavelengths. Same parameters are measured as CO_2 waveform; end tidal CO_2; inspired CO_2 and respiration rate from capnogram as well as the measurement range is identical to the predicate (0 to 100 mmHg). The new Infinity MCable – Mainstream CO_2 Sensor uses the existing legally marketed accessories of the Dräger predicate.

Indication for Use:

The Dräger Infinity MCable Mainstream CO_2 sensor is meant to be used for continuous, real time measurement of CO_2 concentrations of ventilated patients from neonates to adults. This sensor is only intended for use with devices made by Dräger Medical, or with devices which are approved for use with Dräger CO_2 components (Dräger-compatible devices)

Conclusion:

All modifications have been evaluated for safety and effectiveness.
The summary of the design control activities and the risk analysis show that these types of modifications do not change the device operating principle or mechanism of action.
The modifications do not alter the fundamental scientific technology and therefore the safety and effectiveness is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Ulrich Schroeder
Director Regulatory & Clinical Affairs
Draeger Medical AG & Company KG
53/55 Moislinger Allee
Luebeck
Germany D-23542

APR 23 2010

Re: K100941
Trade/Device Name: Infinity MCable
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: March 31, 2010
Received: April 5, 2010

Dear Mr. Ulrich Schroeder:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson
Director
Division of Anesthesiology, General Hospital,
Infection Control and General Hospital,
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Infinity MCable

Indications for Use:

The Dräger Dräger Infinty MCable Mainstream CO2 sensor is meant to be used for continuous, real time measurement of CO2 concentrations of ventilated patients from neonates to adults.
This sensor is only intended for use with devices made by Dräger Medical, or with devices which are approved for use with Dräger CO2 components (Dräger-compatible devices).

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: K100941