K992608

Dräger

AUG 24 1999

file: 510kstate.RTF
Date: July 1999
Author: Frank Clanzett

510(k) SUMMARY
Summary of Safety and Effectiveness

APPLICANTS NAME AND ADDRESS:

Dräger Medizintechnik GmbH
Moislinger Allee 53-55
23542 Lübeck
Germany

APPLICANTS CONTACT PERSON:

Mr. Frank Clanzett
phone: 011-49-451-882-3915
fax: 011-49-451-882-4351
email: frank.clanzett@draeger.com

APPLICANTS CONTACT PERSON IN THE USA

Drager; Inc.
Mr. Harald Kneuer
phone: 215-721-6917
fax: 215-721-6915

DATE THE SUMMARY WAS PREPARED:

July 1999

DEVICE NAME:

Trade Name:	ATC option for Evita 2 dura and Evita 4
Common Name:	Continuous Ventilator
Classification Name:	Ventilator, Continuous (per 21 CFR 868.5895)

LEGALLY MARKETED DEVICE TO WHICH DRÄGER IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Evita 2 dura	- Manufactured by Dräger Medizintechink, Germany
Evita 4	- Manufactured by Dräger Medizintechinik, Germany

DESCRIPTION OF THE DEVICE:

The Evita 4 or the Evita 2 dura are time cycled microprocessor-controlled intensive care ventilators. Both devices can be equipped with the ATC option. ATC means *automatic tube compensation.*

This ventilation mode extension provides a compensation of an endotracheal or tracheostomy tube. It calculates and displays the tracheal pressure from a mathematical model tube model on the basis of selected type of tube and tube internal diameter.

INTENDED USE

The Evita 2 dura and the Evita 4 are time cycled , constant volume, long term, intensive care ventilators for adults and children with a body weight of at least 3 kg.

Intended environment for use of the device
- user facilities
- inner clinical transport

INFORMATION WERE THE SUBSTANTIALLY EQUIVALENT DECISION IS BASED ON

The devices under review have the same intended use as the predicate devices. The patient range and the intended environment for use of the devices are also identical.

The ATC-option was compared with ventilation modes already existed in the predicate devices and deemed to be substantially equivalent.

The general technology, performance specifications, materials used, dimension operating parameters and other characteristics of the devices under review were compared and are substantially equivalent with those of the predicate devices.

Therefore the devices under review are substantially equivalent to the predicate devices concerning safety, efficiency and intended use.

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Frank Clanzett
Regulatory Affairs
Dräger Medizintechnik GmbH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 1999

Mr. Harald Kneuer
Drager Inc.
3136 Quarry Road
Telford, PA 18969

Re: K992608
ATC Option for Evita 2 dura and Evita 4
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: August 2, 1999
Received: August 4, 1999

Dear Mr. Kneuer:

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 (Premarket 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.

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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): unk K992608

Device Name: ATC option for Evita 4 and Evita 2 dura

Indication for Use:

The Evita 2 dura and the Evita 4 are time cycled , constant volume, long term, intensive care ventilators for adults and children with a body weight of at least 3 kg.

Intended environment for use of the device

- user facilities
- inner clinical transport

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

Concurence of CDRH, Office of Device Evaulation (ODE)

Joanna A Weitershausen

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

510(k) Number _____

(Optional Format 3-10-98)

✓ Prescription use