JUL 6 1998

K981773

## SUMMARY OF SAFETY AND EFFECTIVENESS DATA RELATING TO SUBSTANTIAL EQUIVALENCE

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| **Proprietary Name:** | Dräger-Vapor® 19.3 |
| **Classification Name:** | Vaporizer, Anesthesia, Non-heated |
| **Device Class:** | Class II |
| **Initial Distributor:** | North American Dräger<br>3135 Quarry Road<br>Telford, Pennsylvania 18969 USA |
| **Establishment Registration No.:** | 2517967 |
| **Manufacturer:** | Dräger Medizintechnik GmbH<br>Lübeck, Germany |
| **Establishment Registration No.:** | 9611500 |
| **Predicate Devices:** | Dräger-Vapor® 19 (K771899)<br>Dräger-Vapor® 19 for Sevoflurane (K942055) |

### Device Description

The Dräger-Vapor 19.3 (Vapor 19.3) is a concentration calibrated non-heated vaporizer for vaporizing liquid anesthetic agents, designed in a vaporizer chamber bypass arrangement.

### Intended Use

The Vapor 19.3 is intended for vaporization and delivery of a controlled amount of liquid anesthetic agent. The Vapor 19.3 is labeled and calibrated for sevoflurane, halothane, isoflurane, and enflurane.

### Substantial Equivalence

The Vapor 19.3 is substantially equivalent to the currently distributed Dräger-Vapor 19.1 (Vapor 19.1) vaporizers (K771899 and K942055). The Vapor 19.3 and Vapor 19.1 are identical except for the way they are interfaced with the anesthesia machine.

Like the Vapor 19.1, the Vapor 19.3 will be labeled and calibrated for use with sevoflurane, halothane, isoflurane, or enflurane. The dosing of the anesthetic agents remains the same, as does the body of the vaporizer. Both the Vapor 19.3 and 19.1 are available with a permanently attached Key-Index Fill System, or funnel filling device.

The Vapor 19.3 differs from the Vapor 19.1 in the way that the vaporizer may be mounted to the anesthesia machine. The Vapor 19.3 offers a plug-in system which provides for simple installation/

removal of the vaporizer for another. The Vapor 19.3 provides a permanently mounted plug-in adapter which is placed into the mounting pins on the anesthesia machine. The connection to the anesthesia machine is secured by turning its right-angle locking lever until secured in place. The Vapor 19.3 then cannot be removed until actuating the locking lever. This feature is similar to that on the Dräger-Vapor 19.1 with Plug System S Plus (K981472) for connection of the Vapor 19.1 to Selectatec Series Mounting Manifolds.

The exclusion system for the Vapor 19.3 differs from that of the currently distributed Vapor 19.1 in that the Vapor 19.3 is designed for attachment to an anesthesia system with two-position vaporizer mounting and which encompasses an interlock system that prevents more than one vaporizer from being ON at a time. To accomplish this, the cap to the Vapor 19.3 handwheel has been designed with openings (holes) on the sides in which the pin of the interlock mechanism may slide. When the pin is moved to allow one vaporizer to be ON, it prevents the rotation of the handwheel of the second vaporizer, thus preventing two vaporizers from being ON at the same time.

The Vapor 19.3 is intended for the same use and has the same principle of operation as the Vapor 19.1.

Except for different mounting connections and interlock/exclusion systems, the Vapor 19.3 is identical to the Vapor 19.1. Therefore, qualification of the Vapor 19.3 was limited to component qualification testing on those differences to demonstrate compliance to applicable clauses of **ASTM Standard F1161-88**, Sections 8 and 12.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 6 1998

Ms. J. Teresa Dorriety
North American Dräger
3135 Quarry Road
Telford, PA 18969

Re: K981773
Dräger-Vapor 19.3
Regulatory Class: II (two)
Product Code: 73 CAD
Dated: May 19, 1998
Received: May 20, 1998

Dear Ms. Dorriety:

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

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):** K981773

**Device Name:** Dräger-Vapor 19.3 (Vapor 19.3)

**Indications for Use:**

The Dräger-Vapor 19.3 is a non-heated calibrated vaporizer to enrich the fresh gas flow of an anesthesia delivery system with a controlled anesthetic agent vapor. The Vapor 19.3 is indicated for use with enflurane, halothane, isoflurane, and sevoflurane. The Vapor 19.3 is not indicated for use with desflurane or in the breathing circuit of an anesthesia delivery system. Federal law restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981773