K971923

SEP 16 1997

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name: Dräger-Vapor® 2000

Classification Name: Vaporizer, Anesthesia, Non-heated

Device Class: Class II

Initial Distributor: North American Dräger
3135 Quarry Road
Telford, Pennsylvania 18969

Establishment Registration Number: 2517967

Manufacturer: Drägerwerk AG
Lübeck, Germany

Establishment Registration Number: 2517967

Device to which substantial equivalence is claimed: Dräger-Vapor® 19.1 K940255

Device Description:

The Dräger-Vapor 2000 (Vapor 2000) is a concentration calibrated non-heated vaporizer for vaporizing liquid anesthetic agents.

Intended Use:

The Vapor 2000 is intended for vaporization and delivery of a controlled amount of liquid anesthetic agent. The Vapor 2000 is designed and labeled accordingly for use with Enflurane, Isoflurane, Halothane, and Sevoflurane.

Substantial Equivalence:

The Vapor 2000 is substantially equivalent to the Dräger-Vapor 19.1 (Vapor 19.1). Both are concentration calibrated, non-heated vaporizers for vaporizing liquid anesthetic agents with a vaporizing chamber bypass. Both the Vapor 2000 and Vapor 19.1 are available with attached funnel or key-index filling systems. The Vapor 2000 will also be available with the Quik-Fil™ filling system.

The Vapor 2000 differs slightly from the Vapor 19.1 in that the Vapor 2000 has a transport mode which secures the vaporizer from spillage of liquid agent, leakage of anesthetic vapor, and closes off the vaporizing chamber isolating liquid agent or vapors from the rest of the vaporizer.

The Vapor 2000 has a larger reservoir than the Vapor 19.1.

The Vapor 2000 and the Vapor 19.1 have the same intended use and principal of operation and are substantially equivalent.

Qualification of the Vapor 2000 included testing to demonstrate compliance with ASTM Standard F 1161-88, and the effect of temperature, gas flow, duration of use, tilting, and back pressure on concentration output.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 16 1997

Mr. James J. Brennan
North American Drager
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K971923
Dräger-Vapor® 2000
Regulatory Class: II (two)
Product Code: 73 CAD
Dated: August 5, 1997
Received: August 5, 1997

Dear Mr. Brennan:

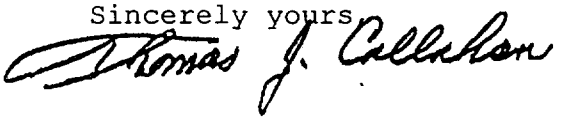
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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/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): K971923

Device Name: Dräger-Vapor® 2000

Indications for Use:

The Dräger-Vapor 2000 (Vapor 2000) is a non-heated calibrated vaporizer designed to enrich the fresh gas flow of an anesthesia delivery system with a controlled amount of anesthetic vapor. Separate models of the single-agent vaporizer are intended for use with one of the following agents: isoflurane, halothane, enflurane, or sevoflurane. The vaporizer is not intended for use with desflurane, or for use within an anesthetic breathing 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 ✓ M. Hogan OR Over-The-Counter Use____
(Per 21 CFR 801.109)

Ath A. Gill

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

510(k) Number _____

(Optional Format 1-2-96)