K973051

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name: Plug System S Plus

Classification Name: Vaporizer, Anesthesia, Non-heated

OCT 30 1997

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: 9611500

Devices to which substantial equivalence is claimed: Dräger-Vapor® 19.1 K942055

Tec 5 Continuous Flow Vaporizer
K942091

Device Description:

The Plug System S Plus is a vaporizer mounting adapter that will allow Dräger Vapor 19.1 vaporizers to be mounted on Selectatec Series Mounted Manifolds.

Intended Use:

The Plug System S Plus is intended for mounting Dräger Vapor 19.1 vaporizers on Selectatec Series Mounted Manifolds.

Substantial Equivalence:

The addition of the Plug System S Plus mounting adapter is the only modification to the Dräger-Vapor 19.1 (K942055).

The 19.1 with Plug System S Plus is also substantially equivalent to the Ohmeda Tec 5 Continuous Flow Vaporizer (Tec 5) (K942091) in that they both incorporate an interlock mechanism designed to be used on Selectatec Series Mounted Manifolds (Selectatec Manifolds). In both systems the interlock mechanism uses extension rods to prevent more than one vaporizer being ON at a time.

The Vapor 19 with Plug System S Plus differs from the Tec 5 in that the Vapor 19 with Plug System S Plus is meant to be installed and removed only by an authorized Dräger Service Representative. A Tec 5 vaporizer maybe installed and removed by a user.

With a Vapor 19 with Plug System S Plus mounted on a Selectatec manifold, the manifold port valves are continually open. The bypass function is internal to the Vapor 19 vaporizer. This is the same bypass route as a Vapor 19 that is mounted to a North American Dräger anesthesia machine.

The Plug System S Plus and the Tec 5 interlock mechanisms have the same intended use and principal of operation.

Qualification of the Vapor 19.1 with Plug System S Plus included testing to demonstrate compliance with ASTM Standard F 1161-88, and the effects of mounting the device on representative Ohmeda anesthesia machines with Selectatec Series Mounted Manifolds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 30 1997

Re: K973051
Drager Vapor® 19.1 with Plug System S Plus
Regulatory Class: II (two)
Product Code: 73 CAD
Dated: October 13, 1997
Received: October 14, 1997

Dear Mr. Brennan:

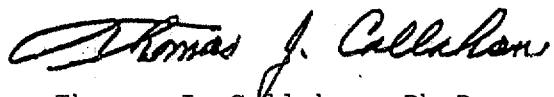
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K973051

Device Name: Plug System S Plus

Indications For Use:

The Plug System S Plus is indicated for mounting Dräger-Vapor 19.1 vaporizer on Selectatec Series Mounted Manifolds. 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 _____

(Optional Format 1-2-96)

Christy Foueman
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973051