K981472

MAY 7 1998

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name:	Plug System S Plus (Modified)
Classification Name:	Vaporizer, Anesthesia, Non-heated
Device Class:	Class II
Initial Distributor:	North American Dräger 3135 Quarry Road Telford, Pennsylvania 18969 USA
Establishment Registration No.:	2517967
Manufacturer:	Dräger Medizintechnik GmbH Lübeck, Germany
Establishment Registration No.:	9611500
Predicate Device:	Plug System S Plus (K973051) Ohmeda Tec 5 (K942091)

Device Description

The Plug System S Plus (Modified) is a vaporizer mounting adapter that will allow Dräger Vapor 19.n vaporizers to be mounted to Selectatec Manifolds. The Plug System S Plus (Modified) is a modification to the currently distributed Plug System S Plus (K973051).

Intended Use

The Plug System S Plus (Modified) is a vaporizer mounting adapter intended for mounting the Dräger Vapor 19.n on Selectatec Series Mounted Manifolds.

Substantial Equivalence

The right-angle lever mechanism and vaporizer specific identification label are the only modifications to the currently distributed Plug System S Plus mounting adapter (K973051).

The Plug System S Plus (Modified) is also substantially equivalent to the Ohmeda Tec 5 Continuous Flow Vaporizer (Tec 5) (K942091) interlock mechanism. Each is designed to be used on Selectatec Series Mounted Manifolds. And, the interlock mechanism of each device uses extension rods to allow only one vaporizer to be ON at a time.

The Plug System S Plus (Modified) differs from the current Plug System S Plus in that the S Plus (Modified) allows for simple replacement without the use of a special tool. With the S Plus

(Modified), locking is performed by means of a right-angle lever. This feature is similar to that of the Tec 5 Continuous Flow Vaporizer.

The principle of operation, performance characteristics and intended use of the S Plus (Modified) are identical to the currently distributed S Plus when mounted to a Selectatec Manifold.

The S Plus has been modified to include a vaporizer specific identification label. Anesthesia systems fitted with a vaporizer identification unit use the label to identify the vaporizer drug type. This is also a feature of the Tec 5 Continuous Flow Vaporizer.

Qualification of the Plug System S Plus (Modified) included testing and/or analysis to demonstrate compliance with **ASTM Standard 1161-88**, Sections 8 and 12 and the compatibility of the mounting device with lever mechanism and vaporizer specific identification label 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

MAY 7 1998

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

Re: K981472
Plug System S Plus (Modified)
Regulatory Class: II (two)
Product Code: 73 CAD
Dated: April 23, 1998
Received: April 24, 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 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

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): K981472

Device Name: Plug System S Plus

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K981472

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

(Optional Format 1-2-96)