

AUG 4 1998

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

K980208

Proprietary Name: Divan Anesthesia Ventilator

Classification Name: Gas-Machine, Anesthesia 73BSZ , 73 CRK

Device Class: Class II

868.5895 (Continuous Ventilator
Anesthesia ventilator)

Manufacturer: North American Dräger
3135 Quarry Road
Telford, Pennsylvania 18969

Establishment Registration Number: 2517967

Devices to which substantial equivalence is claimed:

Narkomed AV2+ Anesthesia Ventilator K953228

Device Description:

The Divan is an electronic ventilator with an integrated breathing system , and operator control panel.

Intended Use:

The Divan is intended to ventilate patients as an integrated part of a North American Dräger anesthesia workstation.

Substantial Equivalence:

The Divan is substantially equivalent to North American Dräger's (NAD's) AV2+ Anesthesia Ventilator (AV2+) in that both are an integral subassembly of Narkomed Anesthesia Systems. They are both volume preset, time cycled, pressure limited ventilators with electronic timing, pneumatic circuitry, and independent controls for frequency, inspiratory to expiratory (I:E) ratio, inspiratory flow rate, tidal volume, and inspiratory pressure limit.

Both the Divan and AV2+ are microprocessor controlled. The Divan utilizes a keypad and incremental encoder as compared to the individual knobs and switches on the AV2+ for adjusting ventilation parameters.

The Divan and the AV2+ provide automatic, manual, and spontaneous modes of patient ventilation. Additionally, the Divan offers synchronized intermittent mandatory ventilation (SIMV), and pressure mode.

The Divan's inspiratory to expiratory (I:E) ratios are adjustable from 1:3 to 2:1. The AV2+ I:E ratios are adjustable from 1:4.5 to 4:1.

The Divan incorporates an integrated breathing system, while the AV2+ works with the breathing system of the Narkomed anesthesia workstation.

In place of the bellows assembly of the AV2+, the Divan uses a piston assembly. Both the bellows assembly of the AV2+ and the piston assembly of the Divan control the amount of tidal volume delivered to the patient during automatic ventilation based on parameters selected by the operator.

The Divan differs from the AV2+ in that: It provides a heater to maintain the warmth of the patient gas in the breathing circuit. During mechanical ventilation the Divan provides more precise control of tidal volume delivery through internal calculations, stops inspiration and starts expiration if the airway pressure increases by more than 5cmH₂O over the set maximum pressure (e.g. if the patient coughs), and automatically performs a periodic leak check. While power is on, the Divan performs self checks. If it detects the same equipment fault twice within 5 minutes it attempts to change to its "safe state". The safe state allows the user to continue to ventilate the patient using the reservoir bag provided with the Divan. If a fault condition occurs that renders the Divan incapable of ventilation, the user can override the Divan and use the reservoir bag to continue ventilating the patient.

Qualification of the Divan included hazard analysis, functional testing, communication testing, environmental testing, and electromagnetic compatibility.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 1998

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

Re: K980208
Divan Anesthesia Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: May 7, 1998
Received: May 8, 1998

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 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.

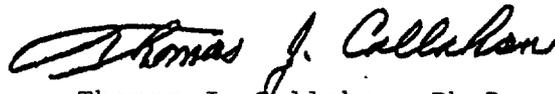
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. James J. Brennan

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): K980208

Device Name: Divan Anesthesia Ventilator (Divan)

Indications for Use:

The Divan is indicated for ventilating patients as an integrated part of specific North American Dräger anesthesia machines. 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)

Lark W. Madov 7-31-98

Prescription Use
(Per 21 CFR 801.109)

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

Over-The-Counter Use

510(k) Number _____

(Optional Format 1-2-96)