

K983635

JAN 11 1999

**Summary of Safety and Effectiveness Data Relating to Substantial Equivalence**

Proprietary Name: Julian Anesthesia Workstation  
Classification Name: Gas-Machine, Anesthesia 73BSZ  
Device Class: Class II  
Manufacturer: Dräger Medizintechnik GmbH  
53/55 Moislinger Allee  
Lübeck, Germany 23558

Establishment Registration Number: 9611500

Devices to which substantial equivalence is claimed:

Narkomed 6000 Anesthesia System	K980553
Divan	K980280
Evita 2 Dura	K970165
Combination Oximeter/Carbon Dioxide Gas Analyzer	K964239

**Device Description:**

The Julian is a continuous flow gas anesthesia system.

**Intended Use:**

The Julian may be used for spontaneous, manually assisted, or automatic ventilation of patients during anesthesia, and delivery of gases and anesthetic vapor. The Julian can monitor oxygen, breathing pressure, respiratory volume, CO<sub>2</sub>, N<sub>2</sub>O, and anesthetic agent identification and concentration.

**Substantial Equivalence:**

Like the NM6000 the Julian is an anesthesia system with integrated monitors providing measurement and display of inspired oxygen, breathing pressure, respiratory volume, CO<sub>2</sub>, N<sub>2</sub>O, anesthetic agent concentration, and agent identification. The NM6000 does not offer pulse oximetry, the Julian pulse oximetry module is also used in the Combination Oximeter/Carbon Dioxide Gas Analyzer.

Both the Julian and the Evita 2 Dura use thermo anemometry to measure respiratory volume.

The theory of operation of the Julian gas delivery system from pipeline to the ventilator function is similar to the Evita 2 Dura.

The Julian can simultaneously deliver up to two gases and one agent, while the NM6000 can simultaneously deliver up to three gases and one anesthetic agent.

Both the Julian and the NM6000 use a compact breathing system. The Julian's system uses a bellows in place of the piston assembly in the NM6000.

Both the NM6000 and the Julian incorporate RS-232 and RS-422 serial communication ports.

Both the Julian and the NM6000 can accommodate up to two vaporizers. The NM6000 also provides a bracket for storage of a third vaporizer on the back of the machine.

The exclusion system of the Julian is identical to the NM6000. Both systems prevent more than one vaporizer from being used at one time.

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



JAN 11 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Gale E. Winarsky  
North American Drager  
3135 Quarry Road  
Telford, PA 18969

Re: K983635  
Julian Anesthesia Workstation  
Regulatory Class: II (two)  
Product Code: 73 BSZ  
Dated: October 15, 1998  
Received: October 15, 1998

Dear Ms. Winarsky:

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 (Pre-market 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" (21CFR 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,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, stylized initial 'T'.

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): K983635

Device Name: Julian Anesthesia Workstation

Indications for Use:

The Julian is indicated as a continuous flow anesthesia system. The Julian may be used for manually assisted, or automatic ventilation, and delivery of gases, anesthetic vapor, and monitoring of oxygen concentration, breathing pressure, and respiratory volume. 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)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR  
Mark Kramer

Over-The-Counter Use

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

(Optional Format 1-2-96)

510(k) Number K983635