K971425

SEP 10 1997

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name: Narkomed M Anesthesia System

Classification Name: Gas-Machine, Anesthesia 73BSZ

Device Class: Class II

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

Establishment Registration Number: 2517967

Devices to which substantial equivalence is claimed:

Narkomed GS Anesthesia System K963994

Device Description:

The NM M is a continuous flow gas anesthesia system.

Intended Use:

The NM M may be used for spontaneous, manually assisted, or automatic ventilation of patients during anesthesia. It may be used for the delivery of gases and anesthetic vapor. The NM M is capable of monitoring oxygen concentration, breathing pressure, and respiratory volume.

Substantial Equivalence:

The NM M is substantially equivalent to the Narkomed GS (NMGS).

The NM M, like the NM GS is an anesthesia system with integrated monitors for oxygen concentration, breathing pressure and respiratory volume. The gas delivery system, ventilator, software, and alarms management of the NM M are the same design that is used on the NM GS. The NM M like the NM GS is available with a Vitalink® serial communication port.

The NM M differs slightly from the NM GS in that; the NM M allows for switching the ventilator drive gas from oxygen to air, the absorber is a single canister absorber, only one Dräger-Vapor® 2000 vaporizer can be mounted on the machine at a time, the manual/automatic selector is activated by turning a knob on the NM M and by moving a lever on the NM GS. The NM M does not provide the option of turning the ventilator on via the

manual/automatic selector valve. The NM M uses the same flat panel display as the NM GS mounted outside of the front panel of the machine. The NM M utilizes the same PEEP valve as the NM GS, but does not include PEEP bypass, which is included on the NM GS. The NM M utilizes dual tapered flowmeters with a range of flows from 0-8 l/min., the NM GS utilizes dual flowmeters (course and fine) with a range of 0-10 l/min. The NM M has no storage drawers or electrical convenience outlets.

The NM M and the NM GS have the same intended use and principal of operation and are substantially equivalent.

Qualification of the NM M included a hazard analysis, system level qualification testing, environmental testing, and electromagnetic compatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 10 1997

Mr. James J. Brennan
North American Drager
3135 Quarry Road
Telford, Pennsylvania 28969

Re: K971425
Narkomed M Anesthesia System
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: July 31, 1997
Received: July 31, 1997

Dear Mr. Brennan:

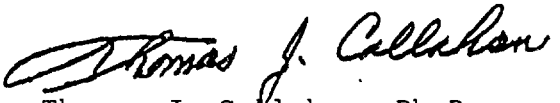
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

DUPLICAT

K971425/A1

510(k) Number (if known): K971425

Device Name: Narkomed M Anesthesia System (NM M)

Indications for Use:

The Narkomed M (NM M) is a continuos flow anesthesia system. The NM M may be used for spontaneous, manually assisted or automatic ventilation of patients during anesthesia. It may be used for the delivery of oxygen, air, and/or nitrous oxide and anesthetic vapor. It is capable of monitoring 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ath A. Gilb

Prescription Device

9/8/97 bazant