K980553

AUG 4 1998

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name: Narkomed 6000 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 4 Anesthesia System K901713

Device Description:

The NM6000 is a continuous flow gas anesthesia system.

Intended Use:

The NM6000 may be used for spontaneous, manually assisted, or automatic ventilation of patients during anesthesia, and delivery of gases and anesthetic vapor. The NM6000 can monitor oxygen, breathing pressure, respiratory volume, CO2, N2O, and anesthetic agent identification and concentration.

Substantial Equivalence:

Like the NM6000 the NM4 is an anesthesia system with integrated monitors providing measurement and display of inspired oxygen, breathing pressure, respiratory volume, CO2, N2O, and anesthetic agent concentration. The gas analysis pod of the NM6000 also identifies the anesthetic agent used and notifies the operator if multiple agents are detected.

The NM6000 does not offer pulse oximetry and noninvasive blood pressure measurements; the NM4 provides this monitoring capability.

The NM6000 monitors respiratory volume using the Narkomed Ultrasonic Flow Sensor. The NM4 utilizes the Spiromed 2.

The theory of operation of the NM6000 gas delivery system is identical to the NM4. The NM6000 like the NM4 can simultaneously deliver up to three gases and one anesthetic agent. The NM6000 differs from the NM4 in that it does not have pipeline connections or gas cylinder yokes for CO2 or Heliox.

Both the NM6000 and the NM4 incorporate RS-232 and RS-422 serial communication ports.

The NM6000 is equipped with the Divan Anesthesia Ventilator, the NM4 uses the AV2+ Anesthesia Ventilator.

The NM6000 can accommodate up to two vaporizers while the NM4 can accommodate up to three. The NM6000 provides a bracket for storage of a third vaporizer on the back of the machine.

The exclusion system of the NM6000 differs from the NM4 in that it uses an operator actuated sliding interlock system in place of the cam and lever system on the NM4. Both systems prevent more than one vaporizer from being used at one time.

Qualification of the NM6000 included hazard analysis, functional, communication, environmental, and electromagnetic compatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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: K980553
Narkomed 6000 Anesthesia Workstation
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: May 14, 1998
Received: May 15, 1998

Dear Mr. Brennan:

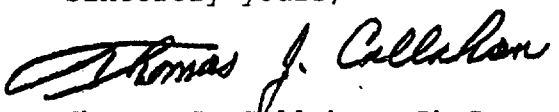
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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

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): K980553

Device Name: Narkomed 6000 Workstation (NM6000)

Indications for Use:

The NM6000 is indicated as a continuous flow anesthesia system. The NM6000 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980553

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

(Optional Format 1-2-96)