K972848

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

OCT 30 1997

Proprietary Name: Narkomed MRI 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
Core-M Omicron Monitor	K960861

Device Description:

The NM-MRI is a continuous flow gas anesthesia system.

Intended Use:

The NM-MRI can be used for spontaneous, manually assisted, or automatic ventilation; delivery of gases and anesthetic vapor; and monitoring oxygen concentration, breathing pressure, and respiratory volume of patients during anesthesia. The NM-MRI is intended for use with the Dräger Vapor® 19.1. The NM-MRI can be used in MRI scanner rooms with magnets of 1.5 tesla or less. It can also be used in MRI scanner rooms with magnets over 1.5 tesla when the Narkomed MRI High Field Mounting Kit installation procedure is followed.

Substantial Equivalence:

The NM-MRI is substantially equivalent to the Narkomed GS (NM GS).

The NM-MRI, like the NM GS is an anesthesia system capable of monitoring oxygen concentration, breathing pressure and respiratory volume. The gas delivery system, absorber and scavenger of the NM-MRI are the same design that is used on the NM GS.

The NM- MRI has been qualified to meet environmental requirements for use in MRI facilities, and like the Ohmeda Excel 210 MRI Compatible Anesthesia System, is intended for use in MRI scanner rooms.

The NM-MRI utilizes non ferromagnetic materials for structural elements and certain components have been shielded and/or relocated.

The monitoring system of the NM-MRI differs from the NM GS by using a specially adapted version of the Core-M Omicron Monitor.

The NM-MRI has the same intended use and principal of operation as the NM GS. The intended environment of use is different in that the NM-MRI will additionally be usable in an MRI environment.

Qualification of the NM-MRI included a hazard analysis, system level qualification testing, environmental testing, electromagnetic compatibility testing, and testing in an MRI environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 1997

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

Re: K972848
Narkomed MRI Anesthesia System
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: August 1, 1997
Received: August 1, 1997

Dear Mr. Hokanson:

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

510(k) Number (if known): K972848

Device Name: Narkomed MRI Anesthesia System (NM-MRI)

Indications For Use:

The NM-MRI is a continuous flow anesthesia system. The NM-MRI may be used for spontaneous, manually assisted, or automatic ventilation, and delivery of gases, anesthetic vapor, and monitoring of oxygen concentration, breathing pressure, and respiratory volume. The NM-MRI is indicated for use with the Dräger Vapor® 19.1. The NM- MRI may be used in MRI scanner rooms with magnets up to 1.5 tesla, and with magnets over 1.5 tesla when installed using the NM-MRI High field Mounting Kit. 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)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

Division Sign-Off
Division of Cardiovascular, Respiratory,
Neurological Devices
Number K972848