K001488

JUN - 9 2000

SUMMARY OF SAFETY AND EFFECTIVENESS DATA RELATING TO SUBSTANTIAL EQUIVALENCE

Proprietary Name:	Narkomed MRI Anesthesia System
Classification Name:	Gas Machine, Anesthesia – 73 BSZ
Device Class:	Class II
Initial Distributor:	Draeger Medical, Inc. 3135 Quarry Road Telford, Pennsylvania 18969 USA
Establishment Registration No.:	2517967
Predicate Device:	Narkomed MRI Anesthesia System – K974828 Narkomed GS Anesthesia System – K963994

Device Description:

The modified 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 Dräger-Vapor® 19.n vaporizers. The NM-MRI can be used in MRI scanner rooms with magnets up to 1.5 tesla.

Substantial Equivalence:

The modified Narkomed MRI Anesthesia System is substantially equivalent to the currently distributed Narkomed MRI Anesthesia System. As the currently distributed device, the modified MRI has the following features:

- Monitors oxygen concentration, breathing pressure and respiratory volume;
- Qualified to meet environmental requirements for use in MRI facilities;
- Intended for MRI scanner rooms;
- Utilizes non-ferromagnetic materials for structural elements; and
- Shielded or relocated certain components for EMC.

The difference between the current and the modified NM-MRI is a new VPO monitor.

Qualification of the modified NM-MRI included hazard analysis, system level qualification, and environmental testing. Image compatibility testing confirmed that the NM-MRI does not negatively impact the diagnostic quality of images produced while the anesthesia machine is on and cycling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2000

Mr. Jim Brennan
Director, Regulatory Affairs
Dreager Medical, Inc.
3135 Quarry Road
Telford, PA 18969

Re: K001488
Narkomed MRI Anesthesia System
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: May 11, 2000
Received: May 12, 2000

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,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001488

Device Name: Narkomed MRI Anesthesia System

Indications for 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 Dräger-Vapor® 19.n vaporizers. The NM-MRI can be used in MRI scanner rooms with magnets up to 1.5 tesla.

Mark N Milhouse

for **(Division Sign-Off)**
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001488

(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 _____
(Per 21 CFR 801.109)