

AUG 29 2002

K002031

**SUMMARY OF SAFETY AND EFFECTIVENESS DATA RELATING TO  
SUBSTANTIAL EQUIVALENCE**

**Proprietary Name:** Narkomed MRI-2 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-2 Anesthesia System – K003579

**Device Description:**

The Narkomed MRI-2 (NM-MRI-2) is a continuous flow gas anesthesia system.

**Indications for Use:**

The NM-MRI-2 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-2 is intended for use with Dräger-Vapor® vaporizers. The NM-MRI-2 can be used in MRI scanner rooms with magnet strengths up to 3.0 tesla without distance limitations.

**Substantial Equivalence:**

The NM-MRI-2 is identical to the currently distributed Narkomed MRI-2 Anesthesia System (K003579). Qualification testing has been performed to expand the indications for use from “can be used in MRI scanner rooms with magnet strengths up to 1.5 tesla” to “can be used in MRI scanner rooms with magnet strengths up to 3.0 tesla.” A bain circuit adapter with a MRI compatible breathing pressure gauge has also been added as an option.

Qualification of the NM-MRI-2 included the completion of a hazard analysis and system level qualification. Qualification testing confirmed that, in a 3.0 tesla environment, the NM-MRI-2 does not exceed attractive force limitations and does not negatively impact the diagnostic quality of images produced by the MRI scanner or disturb the homogeneity of the main magnetic field. Qualification testing also confirmed that a 3.0 tesla MRI scanner does not affect the operation/functionality of the NM-MRI-2.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 29 2002

Mr. Michael Kelhart  
Regulatory Affairs Project Manager  
Draeger Medical, Incorporation  
3135 Quarry Road  
Telford, Pennsylvania 18969

Re: K022031

Trade/Device Name: Narkomed MRI-2 Anesthesia System, Model NM-MRI-2  
Regulation Number: 868.5160  
Regulation Name: Gas Machine, Anesthesia  
Regulatory Class: II  
Product Code: BSZ  
Dated: June 20, 2002  
Received: June 21, 2002

Dear Mr. Kelhart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

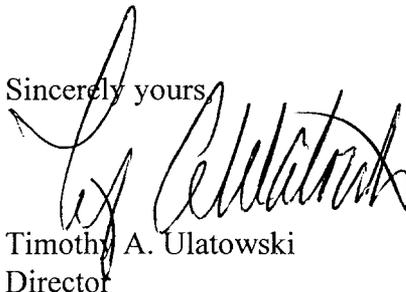
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Timothy A. Ulatowski  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K022031

Device Name: Narkomed MRI-2 (NM-MRI-2) Anesthesia System

**Indications for Use:**

The NM-MRI-2 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-2 is intended for use with Dräger-Vapor® vaporizers. The NM-MRI-2 can be used in MRI scanner rooms with magnet strengths up to 3.0 tesla without distance limitations.

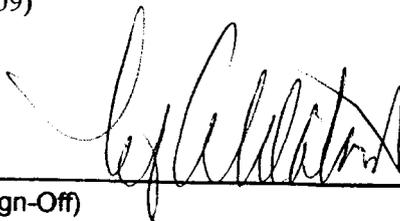
**(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)**

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use  \_\_\_\_\_



\_\_\_\_\_  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K022031

(Optional Format 1-2-96)