APR 2 6 2004

K033498

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name:Narkomed 6400 w/ Integrated Patient Monitoring

Classification Name:Gas-Machine, Anesthesia 73BSZ

Device Class:Class II

Manufacturer:Draeger Medical Inc.
3135 Quarry Road
Telford, Pennsylvania 18969

Establishment Registration Number:2517967

Devices to which substantial equivalence is claimed:
Narkomed 6000 w/ Cardiovascular and Strip Chart Recorder Pods K993826
Marquette SL Series Transport Remote Acquisition (TRAM) K921669
Solar 7000/8000 System K993757

Device Description:

The Narkomed 6400 w/ Integrated Patient Monitoring is a continuous flow gas anesthesia system with cardiovascular monitoring.

Intended Use:

The Narkomed 6400 w/ Integrated Patient Monitoring (NM6400 w/ IPM) may be used for spontaneous, manually assisted, or automatic ventilation of patients during anesthesia, and delivery of gases and anesthetic vapor. The NM6400 w/ IPM can monitor oxygen, breathing pressure, respiratory volume, CO2, N2O, cardiovascular parameters and anesthetic agent identification and concentration and provide portioned data.

Substantial Equivalence:

The base functionality of the product line remains essentially the same. Like the NM6000 w/ CV Pod, the NM6400 w/ IPM uses the TRAM technology for cardiovascular monitoring capabilities. The NM6400 w/ IPM differs in that it also uses TRAM technology to provide Wedge Pressure information.

The NM6400 w/ IPM also provides the ability to do cardiac trial calculations. Several messages for user clarification were added, along with an alarm indicating the presence of two agents.

Qualification of the NM6400 w/ IPM included a hazard analysis and system level qualification testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2004

Mr. Gale Winarsky
Regulatory Affairs Project Manager
Draeger Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K033498
Trade/Device Name: Narkomed 6400 Anesthesia Workstation w/IPM
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: February 23, 2004
Received: February 24, 2004

Dear Mr. Winarsky:

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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033498

Device Name: Narkomed 6400 Anesthesia Workstation w/ IPM

Indications for Use:

The NM6400 w/IPM is indicated as a continuous flow anesthesia system. The NM6400 w/IPM may be used for manually assisted, or automatic ventilation, and delivery of gases, anesthetic vapor, and monitoring of; oxygen concentration, breathing pressure, respiratory volume, cardiovascular parameters, anesthetic agent identification and concentration and provides printed data. Federal law restricts this device to sale by or on the order of a physician.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K033498