MAR 2 3 2000

K993826

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

Establishment Registration Number: 2517967

Devices to which substantial equivalence is claimed:

Narkomed 6000 Anesthesia Workstation K980553
Marquette SL Series Transport Remote Acquisistion K921669
Narkomed 4 Anesthesia System K901713

Device Description:

The NM6000 Anesthesia Workstation has been modified to include optional Cardiovascular and Strip Chart Recorder Pods.

Intended Use:

The NM6000 with optional Cardiovascular and Strip Chart Recorder Pods (NM6000 w/ CV & SCR) may be used for spontaneous, manually assisted, or automatic ventilation of patients during anesthesia, and delivery of gases and anesthetic vapor. The NM6000 w/ CV & SCR can monitor oxygen, breathing pressure, respiratory volume, CO2, N2O, cardiovasuclar parameters and anesthetic agent identification and concentration, and provide printed data.

Substantial Equivalence:

The base functionality of the NM6000 product line remains essentially the same.

The NM6000 CV pod uses a combination of Draeger Medical Inc. electronics and TRAM technology for the cardiovascular monitoring parameters. Both products are designed to monitor a patient's basic cardiovascular physiological parameters and offer the following functions:

Multiple ECG lead monitoring,
Dual temperature channels,

Invasive blood pressure channels,
A noninvasive blood pressure channel,
Thermodilution cardiac output,
Pulse oximetry,
ST segment analysis,
Synchronized cardioversion

Like the TRAM, the CV pod provides and receives information through an interface to a host.

The NM6000 CV pod differs from the TRAM technology in that respiration, arrhythmia detection and associated alarms, will not be functional in NM6000 CV pod.

The NM6000 SCR pod uses a SCR similar to the one currently marketed in the Narkomed 4 Anesthesia System. They differ only in that the NM6000 SCR uses the standard parallel to parallel communication, where the NM4 SCR is modified to allow serial to parallel communication.

Qualification of the NM6000 w/ CV & SCR 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

MAR 23 2000

Mr. Gale E. Winarsky
Dräger Medical, Inc.
3135 Quarry Road
Telford, PA 18969

Re: K993826
Narkomed 6000
Regulatory Class: II (two)
Product Code: 73 BSZ, 74 MLC
Dated: March 1, 2000
Received: March 2, 2000

Dear Mr. Winarsky:

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,

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

Enclosure

510(k) Number (if known): K993826

Device Name: Narkomed 6000 Anesthesia Workstation w/ Optional Cardiovascular and Strip Chart Recorder Pods (NM6000 w/ CV & SCR)

Indications for Use:

The NM6000 w/ CV & SCR in indicated as a continuous flow anesthesia system. The NM6000 w/ CV & SCR 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.

(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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K993826