K973949

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

FEB - 6 1998

Proprietary Name: Perioperative Data Managment 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: O.R. Data Manager K900937

Device Description:

The PDMS may be used for receiving, recording and displaying monitoring information from anesthesia systems, other medical devices in the operating room (OR), and through the hospital network and manual entry.

Intended Use:

The Perioperative Data Managment System (PDMS) may be used as a data management system for electronically collecting, recording, and displaying anesthesia information

Substantial Equivalence:

The PDMS is substantially equivalent to the OR Data Manager (ORDM).

The PDMS and the ORDM have the same intended use and principal of operation and are substantially equivalent.

Qualification of the PDMS included a hazard analysis, system level qualification testing, environmental testing, and electromagnetic compatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 1998

Mr. James J. Brennan
Director, Regulatory Affairs
North American Drager
3135 Quarry Road
Telford, PA 18969

Re: K973949
Perioperative Data Management System (PDMS)
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: December 13, 1997
Received: December 17, 1997

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 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

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

510(k) Number (if known): K973949

Device Name: Perioperative Data Management System (PDMS)

Indications For Use:

The Perioperative Data Management System is indicated for electronically collecting, displaying, and recording perioperative information. 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)

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973949