K974193

JAN 28 1998

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name: Narkomed Ultrasonic Flow Sensor

Classification Name: Monitoring Spirometer

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: Spiromed 2 K851620

Device Description:

The Narkomed Ultrasonic Flow Sensor mounts to the expiratory valve fitting on Narkomed Anesthesia Systems and ultrasonically measures respiratory flow rate.

Intended Use:

The Narkomed Ultrasonic Flow Sensor is intended for measuring the flow rate of gas through the patient breathing circuit to determine tidal volume, minute volume, and respiratory rate.

Substantial Equivalence:

The Narkomed Ultrasonic Flow Sensor is substantially equivalent to the Spiromed 2.

The Narkomed Ultrasonic Flow Sensor and the Spiromed 2 have the same intended use. The principle of operation of the Narkomed Ultrasonic Flow Sensor differs in that it measures ultrasonic pulses while the Spiromed 2 measures electronic pulses generated by positive displacement. There have been no new questions of safety and efficacy raised as a result of the Narkomed Ultrasonic Flow Sensor technology. Therefore the Narkomed Ultrasonic Flow Sensor and the Spiromed 2 are substantially equivalent.

Qualification of the Narkomed Ultrasonic Flow Sensor included a hazard analysis, functional and communication 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

JAN 28 1998

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

Re: K974193
Narkomed Ultrasonic Flow Sensor
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: November 6, 1997
Received: November 7, 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, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974193

Device Name: Narkomed Ultrasonic Flow Sensor

Indications For Use:

The Narkomed Ultrasonic Flow Sensor is indicated for measuring the respiratory flow rate of gas through the patient breathing circuit. 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 K974193