K024213

MAR 2 3 2004

510 (k) Summary
as required by section 807.92(c)

Subscribers Name & Address

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Contact Person for this submission: Mikael K. Johansson, Regulatory Affairs Anesthesia

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51 Valleystream Parkway, Malvern PA 19355

Trade Name

KION Anesthesia Workstation - Extended Modes Functionality

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Gas machine, Anesthesia	73 BSZ	II	21 CFR 868.5160
Gas machine, Analgesia	73 ELI	II	21 CFR 868.5160
Arrhythmia detector and alarm	74 DSI	III	21 CFR 870.1025
Non-rebreathing valve	CBP	II	21 CFR 868.5870

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
KION Anesthesia Workstation	K973971
Modification to KION Anesthesia Workstation	K001315
KION Anesthesia Workstation - Pressure Control Functionality	K010923
Servo Ventilator 300A	K970839
Servo Ventilator 900C Siemens-Elema AB	K811102
Servo Anesthesia Circle 985 Siemens-Elema AB	K893786

Other relevant submissions

Devices	*510(k) #*
Servo-I	K010925
Servo Ventilator 300 Auto Mode	K970839

Device Description (for detailed description see Section F)

The KION Anesthesia Workstation - Extended Modes Functionality, adds primarily new functions for Pressure Support and Non-rebreathing to the already cleared KION Anesthesia Workstation with Pressure Control Functionality.

Intended Use:

The KION Anesthesia Workstation is intended for general anaesthesia use. The KION Anesthesia Workstation will deliver operator set concentrations of oxygen and anesthesia gases as well as deliver controlled breaths to the patient with either a constant or a decelerating flow pattern. KION Anesthesia Workstation is also intended to allow for the provision of manual ventilation and spontaneous ventilation.

Intended Operator:

The KION Anesthesia Workstation is intended for use by Healthcare professionals who are trained in the administration of anesthesia

Intended Patient Populations:

The KION Anesthesia Workstation is intended for use on the neonatal to adult patient populations in all ventilation modes. The exception is in Volume Control in the Circle System, where it is not intended for use on neonates.

Intended Use Environment:

The KION Anesthesia Workstation is intended to be used in the environments where anesthesia is to be administered by Healthcare professionals trained in administering anesthesia.
It is not intended for transport use in ambulances or helicopters. It is not intended for use in Magnetic Resonance Imaging Suites.

Summary of technological characteristics of Device and Predicate Device:

The KION Anesthesia Workstation - Extended Modes Functionality is substantially equivalent to it's previous versions KION Anesthesia Workstation (K973971), Modification to KION Anesthesia Workstation (K001315) and KION Anesthesia Workstation with Pressure Control Functionality (K010923) as well as to the predicate devices, the Siemens Servo Ventilator 900 C (K811102), Siemens Servo Ventilator 300 (K902859), and Servo Anesthesia Circle 985 (K893786).

The technical differences are more of physical dimensions (compared to the SV900 and SV300), simplified user interaction for fast and reliable user operation, and use of modern components. The technology used is assessed and the results show that the KION anesthesia Workstation – Extended Modes functionality has the equivalent clinical performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2004

Mr. Jamie Yieh
Manager, Regulatory Affairs
Maquet Inc.
c/o Siemens Medical Solutions USA, Inc.
1140 Route 22 East, Suite 202
Bridgewater, NJ 08807

Re: K024213
Trade/Device Name: Siemens Kion Anesthesia Workstation
Regulation Number: 870.1025
Regulation Name: Physiological Patient Monitor w/ Arrhythmia Detection or Alarms
Regulatory Class: III
Product Code: DSI, BSZ
Dated: December 23, 2003
Received: December 24, 2003

Dear Mr. Yieh:

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.

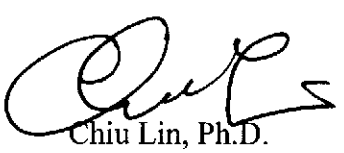
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

510(k) Number (if known): K024213

Device Name: KION Anesthesia Workstation

Indications For Use:

Use of the KION Anesthesia Workstation is indicated in order to allow for the provision of anesthesia to the neonatal to adult patient populations in all ventilation modes except for Volume Control in the Circle System, where it is not intended for use on neonates. It is intended to be used in an environment where patient care is provided by Healthcare professionals, trained in the administration of anesthesia, when the professional determines that a device is required to assist the breathing of a patient undergoing anesthesia. The device can be used to administer anesthesia while controlling the entire ventilation for patients without any ability to breath, as well as supporting patients with reduced ability to breath.

MRI Compatibility Statement:

Siemens KION anesthesia Workstation is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

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

510(k) Number: K024213