SEP 1 3 1999



K973971

## 510(k) SUMMARY
as required per 807.92(c)

1. Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (508) 750-7500
Fax: (508) 777-3398

Official Correspondent:
David Simard, Director
Quality Assurance & Regulatory Affairs

Contact person for this submission:
Wulf R. Trepte
Quality Assurance
Date submission was prepared: 16/10/97

2. Trade Name, Common Name and Classification Name:

A. Trade Name:

KION Anesthesia System

B. Common Name, Classification Name, Class and Regulation Number:

| Common Name | Classification Number | Class | Regulation Number |
|---|---|---|---|
| Gas-machine, Anesthesia | 73BSZ | II | 21 CFR 868.5160 |
| Gas-machine, Analgesia | 73ELI | II | 21 CFR 868.5160 |
| Cardiac monitor | 74DRT | II | 21 CFR 870.2300 |
| Pulse rate monitor | 74BWS | II | 21 CFR 870.2300 |
| Pulse oximeter | 74DQA | II | 21 CFR 870.2700 |
| Breathing Frequency Monitor | 73BZQ | II | 21 CFR 868.2375 |
| Clinical Electronic Thermometer | 80BWX | II | 21 CFR 880.2910 |
| Indwelling Blood Pressure Monitor | 74CAA | II | 21 CFR 870.1110 |
| Heart Rate Monitor, Neonatal | 74FLO | II | 21 CFR 870.2300 |
| Ventilatory Effort Monitor (Apnea Detector) | 73FLS | II | 21 CFR 868.2375 |
| Monitor Blood Pressure, Neonatal, Invasive | 74FLP | II | 21 CFR 870.1110 |
| Arrhythmia detector & Alarm | 74DSI | III | 21 CFR 870.1025 |
| Medical Cathode-Ray Tube Display | 74DXJ | II | 21 CFR 870.2450 |
| ST Segment Monitor with Alarm | 74MLD | III | 21 CFR 870.1025 |
| Non-indwelling Blood Pressure Monitor | 74DXN | II | 21 CFR 870.1130 |
| End-tidal Carbon-Dioxide Monitor | 73CCK | II | 21 CFR 868.1400 |





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**S-171 95 Solna**
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3. Predicate Device Identification:

| *Legally marketed devices to which equivalence is being claimed* | *510(k) #* |
|---|---|
| Siemens Servo Ventilator 900C | K841529 |
| Servo Ventilator 900C/D Electronic gas supply unit | K871354 |
| Servo Ventilator 900C/D CAV 1.0 Master Program Flow & Prs, CO2 Lung Monitor | K861707 |
| Servo Ventilator 900C/D P.C. Interface | K852771 |
| Servo Ventilator 900C/D CAV 4.0 Software Servo Graphics | K923444/A |
| Servo Ventilator 900C/D Man. Vent. Acc. | K854036 |
| Servo Ventilator 900C/D/E CAV 3.0 Software | K890932 |
| Siemens Servo Anesthesia Circle 985 | K893786 |
| Siemens Vaporizers 950/951/952 | K841157 |
| Ohmeda Tec5 Vaporizer | K942091 |
| Siemens Servo Ventilator 300 | K960010 |
| Siemens SC9000/SC9015 Bedside Monitoring System | K946306 |

4. Device Description:

KION is a modular anesthesia system. It is available as a set of hardware and software options, which can be added to take the system from being a low-cost, general purpose anesthesia machine, to a complete state-of-the-art anesthesia workstation. This gives the opportunity to specify a system and then upgrade and modify the system as needs change in the future. The KION anesthesia system is designed to enable the operator to work with the basic components of an anesthesia system in the most suitable way for each patient case. As such, the system is mounted on wheels to allow it to be easily moved into an optimum position, where many of the components can also be individually rotated. The KION system is intended for use on adult and pediatric patients

Physically, the KION consists of three main sections:

1. The **Trolley** which contains the main pneumatic inlets, power supply and power inlets, battery, communication ports, and the gas delivery system.
2. The **Column** consists of a revolving Vaporizer Holder, Servo Bellows Absorber and Patient Cassette.
3. The **Integrated User Interface** consists of the Control Panel and the Monitor.

The KION offers the following standard ventilation capabilities:

- Volume controlled ventilation
- Manual ventilation

5. Intended Use:

The intended use for the KION is as a modular anesthesia system for use on Adult and Infant patient populations. The unit is designed to be used in the operating room or any other hospital location where administration of anesthesia is necessary.





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## 6. Table of Device Similarities and differences to predicate device

| | | | |
|---|---|---|---|
| *Manufacturer* | Siemens-Elema AB, Electromedical Systems Division | Siemens-Elema AB, Electromedical Systems Division | _ |
| *510(k) number* | **Predicate devices**<br>• Siemens Servo ventilator 900C - **K841529**<br>• Siemens Servo Ventilator 300 - **K960010**<br>• Servo Anesthesia Circle 985 -**K893786.**<br>• Siemens Vaporisers 950, 951, 952 - **K841157.**<br>• Ohmeda Tec 5 vaporiser - **K942091.**<br>• Siemens Servo Screen - **K960168** | ***Modified Device***<br>**Kion** Anesthesia System<br>K number to be decided | _ |

| *Parameters General* | *Predicate devices: All* | *Modified Device*<br>**Kion** Anesthesia System | *Explanation of the differences compared to the Predicate devices* |
|---|---|---|---|
| Applications and Intended Use | Infants to Adults | Same | - |
| Gas Delivery System | Pneumatic Powered Servo Controlled "Bag in Bottle" system. | Same | - |
| Battery Back up | No | Yes | Battery backup for the 900C is only available with an external system. |

| *Parameters Gas Dosage* | *Predicate devices*<br>Siemens Servo ventilator 900C - **K841529**<br>Servo Anesthesia Circle 985 - **K893786.** | *Modified Device*<br>**Kion** Anesthesia System | *Explanation of the differences compared to the Predicate devices* |
|---|---|---|---|
| Fresh gas dosage Range<br>Accuracy | Range:500 ml/min - 40 l/min<br>+ /- 10% | Range:100 ml/min - 18lpm<br>Same | Enhanced functionality on Kion for low flow applications<br>- |
| Oxygen Percent | 21% / 25% - 100% (Air / $N_2O$) | 21% / 28% - 100% (Air / $N_2O$) | Enhanced anti-hypoxic measures |
| Gas Mixture Setting | $0_2$/Air or 02/$N_20$ | Same | - |
| Anti-hypoxia device (Limits $O_2/N_2O$ fresh gas ratio) | Yes | Same | _ |
| Ventilator Integral | Yes | Same | _ |

| **Anesthetic Vapour Delivery Modules** | *Predicate devices*<br>**Siemens Vaporizers 950/951/952 and Ohmeda Tec5** | *Modified Device*<br>**Kion** Anesthesia System Vaporizers | *Explanation of the differences compared to the Predicate devices* |
|---|---|---|---|
| **Operating Principle** | High pressure precision injector | Same | _ |
| **Vaporizer mounting** | Single vaporizer mounting | Magazine for three vaporizers mounting | Enhanced functionality. |





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| **Breathing Systems** | *Predicate devices* **SV 900 and Servo Anesthetic Circle 985** | *Modified Device* **Kion** Anesthesia System | *Explanation of the differences compared to the Predicate devices* |
|---|---|---|---|
| Circle System | Yes | Same | - |
| Auxiliary Fresh Gas Outlet | No | Yes | Enhanced functionality to support external breathing systems (e.g. Bain, T-piece) |
| Adjustable Pressure Regulating (APL) valve | No | Adjustable to 90 cm $H_2O$ | Improved functionality |

| **Ventilation Modes** | *Predicate devices* **SV 900C** | *Modified Device* **Kion** Anesthesia System | *Explanation of the differences compared to the Predicate devices* |
|---|---|---|---|
| Manual | Yes | Same | - |
| Volume Controlled Ventilation | Yes | Same | - |
| Pressure Controlled Ventilation | Yes | No | Planned for future enhancement in Kion |
| Pressure Support | Yes | No | Planned for future enhancement in Kion |

| **Ventilatory Control Settings** | *Predicate devices* **SV 300** | *Modified Device* **Kion** Anesthesia System | *Explanation of the differences compared to the Predicate devices* |
|---|---|---|---|
| Preset Minute Volume | 0.5 - 45LPM | Same | |
| Tidal Volume | 2 - 1500 ml | 20 - 1500 ml | Altered functionality, no neonatal capability on Kion. |
| CMV Rate | 0. 5 - 120 | 6 - 99 | Enhanced functionality due to specific clinical anesthesia requirements |
| I:E Ratio | 1:4 - 4:1 in seven steps. | 1:3 - 4:1 in five steps. | Enhanced functionality due to specific clinical anesthesia requirements |
| Pause Time | 0, 5, 10, 20, 30% of cycle | 10% of cycle in Volume Control Mode ( except for I:E - 4:1 = 0%) | Enhanced functionality due to specific clinical anesthesia requirements |
| Inspiratory Gas Flow | Maximum 180 lpm | Same | - |

| **Monitored Ventilatory & Respiratory parameters** | *Predicate Devices* **SV 900 and Servo Screen 390** | *Modified Device* **Kion** Anesthesia System | *Explanation of the differences compared to the Predicate devices* |
|---|---|---|---|
| Inspired Tidal Volume | Yes | Same | - |
| Expired Tidal Volume | Yes | Same | - |
| Rate | Yes | Same | - |
| Peak airway Pressure | Yes | Same | - |
| Mean Airway Pressure | Yes | Same | - |
| Pause Pressure | Yes | Same | - |
| PEEP/CPAP | Yes | Same | - |
| Airway pressure / Analogue Display | Yes | Same | - |

| **Ventilatory Alarms** | *Predicate Device* **SV900** | *Modified Device* **Kion** Anesthesia System | *Explanation of the differences compared to the Predicate devices* |
|---|---|---|---|
| | This device has the following alarms: High Airway Pressure, High Continuous Airway Pressure, Disconnect, Low Minute Volume, Low 02 Concentration | Same | Enhanced functionality. In addition Kion also have the following alarms: Low Air Supply Wall and Tank, Low 02 Supply Wall and Tank, Low 02 Supply Wall and Tank, Low N20 Supply Wall and Tank, High Air Supply Wall and Tank, High 02 Supply Wall and Tank, High N20 Supply Wall and Tank, Low Battery Capacity |





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7. Assessment of non-clinical performance data for equivalence:
See the testresults under section In-house Testing, Section T, in this submission.

8. Assessment of clinical performance data for equivalence:
Clinical trials ongoing.

9. Biocompatability:
Not applicable

10. Sterilization:
Not applicable

11. Standards and Guidances:

KION complies to the following standards:

- IEC 601-1 (EN 60601-1) Medical Electrical Equipment, part 1: General requirements for safety.
- IEC 601-1-1 (EN 60601-1-1) Medical Electrical Equipment, part 1.1: Safety Requirements for medical electrical systems.
- IEC 601-1-2 (EN 60601-1-2) Medical Electric Equipment, part 1.2: Electromagnetic Compatibility- Requirements and Tests
- ISO/DIS 8835-1.2 (Forthcoming IEC 60601-2-13, 2nd Ed.) Anesthesia Workstations and Their Components.
- prEN 794-1 Lung ventilators-Part 1: Particular Requirements for Critical Care Ventilators.
- ISO 7767 Oxygen monitors for monitoring patient breathing mixtures- Safety Requirements.





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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 3 1999

Mr. David Simard
Simens Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923

Re: K973971
KION Anesthesia System
Regulatory Class: III (three)
Product Code: 73 BSZ and 74 DSI
Dated: July 20, 1999
Received: July 21, 1999

Dear Mr. Simard:

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,

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): K973971

Device Name: KION Anesthesia System

Indications for Use:

Use of the KION Anesthesia System is indicated for adult or infant populations 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 the patient. This device can be used to administer anesthesia while controlling the entire ventilation for patients without any ability to breathe, as well as for supporting patients with reduced ability to breathe.

**MRI Compatibility Statement:**

Siemens KION is not compatible for us in a MRI magnetic field.

(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 K973971