K980884

510(k) Summary and Certification

Submitter's Name and Address

Siemens-Elema AB
Röntgenvägen 2
S-171 95 Solna
Sweden

Official Correspondent

Mr. David Simard

Telephone 978-907-7737
Telefax 978-777-3398

Contact Person for this Submission

Mr Wulf R. Trepte

Telephone 011-46 8 730 72 28
Telefax 011-46 8 98 63 05

Device Name

Common Name:	Sevoflurane Vaporizer 953
Classification Name:	Anesthetic Vaporizer
Regulation Number:	21 CFR 868.~~5580~~ 5880
Classification Number:	~~73BSZ~~ 73CAD
Class:	Class II

Establishment Registration Number

The Establishment Registration Number for Siemens-Elema AB is: 8010042

Manufacturing Facility Address

Siemens-Elema AB
S-171 95 Solna
Sweden

Reason for Pre-market Notification

The reason for this pre-market notification is an expanded indication to the existing device.

Predicate Device

The legally marketed device to which equivalence is being claimed is:

Siemens Vaporizers 950/951/952, i.e Halothane Vaporizer 950, Enflurane Vaporizer 951, Isoflurane Vaporizer 952, they were found Substantially Equivalent on June 7, 1984 (Premarket Notification K841157).

Device Description

The Sevoflurane Vaporizer 953 is an anesthetic vaporizer used together with Siemens Servo Ventilator 900 in anesthetic applications. It is a modification of the Siemens Vaporizers 950/951/952.

The modifications made are:

- At the knob a scale for Sevoflurane is added. The scale indicates concentration values from 0.2% to 8%.
- The knob scale, label and filling mechanism, are yellow color coded.
- To reach the concentration values 8% the inside diameter of a capillary tube is 0.36mm instead of 0.30mm as in the other vaporizers

Intended Use

Purpose and function of the Sevoflurane Vaporizer SV953:

The **Sevoflurane Vaporizer SV 953** is designed for use with the Servo Ventilator 900 and for vaporizing the liquid anesthetic agent sevoflurane in conjunction with the controlled administration of anesthetic gas mixtures during surgery.

Intended Operator:

The **Sevoflurane Vaporizer SV953** is intended to be used by Healthcare providers, i.e. Physicians, Nurses and Technicians.

Intended Patient Populations:

The **Sevoflurane Vaporizer SV953** is intended for general and critical ventilatory to be used on Adult, Pediatric, Infant and Neonatal populations.

Intended Use Environment:

The **Sevoflurane Vaporizer SV953** is intended to be used in the environment where patient care is provided by Healthcare Professionals. The unit is designed to be used at the bedside. It is not intended for transport use in ambulances or helicopters in the U.S. market.

Siemens-Elema AB
Electromedical Systems Division

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SWEDEN

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510(k) Notification

Siemens Sevoflurane Vaporizer SV 953

Substantial Equivalence:

The enhanced functionality for the **Sevoflurane Vaporizer SV953** is equivalent to the Siemens **Halothane Vaporizer HV950**.

The Siemens **Halothane Vaporizer HV950** was granted pre-market approval under 510(k) file number K841157.

MRI Compatibility Statement:

The Sevoflurane Vaporizer SV953 is not compatible for use in a MRI magnetic field.

Biocompatibility

Not applicable

Sterilization

Not applicable

Specific Standards & Guidances

Siemens Sevoflurane Vaporizer SV 953 complies with the following standards:

- ISO/DIS 8835-1.2
- ISO 5360

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Comparison of Technological Characteristics

The hardware modification, compared to the predicate device, is:

- At the knob a scale for Sevoflurane is added. The scale indicates concentration values from 0.2% to 8%.
- The knob scale, label and filling mechanism, are yellow color coded.
- To reach the concentration values 8% the inside diameter of a capillary tube is 0.36 mm instead of 0.30 mm as in the other vaporizers

The functionality of the Sevoflurane Vaporizer SV 953 is identical to the functionality of the Siemens Vaporizers 950/951/952; i.e Halothane Vaporizer 950, Enflurane Vaporizer 951, Isoflurane Vaporizer 952.

Tests Used in Determination of Substantial Equivalence

The design of the Seveflurane Vaporizer SV 953 has been thoroughly validated. All different settings of the new expanded indications has been tested, all test were passed according to criteria that are equal or more stringent than the test criteria which were applied to the predicate device.

Conclusion

Analysis and tests have shown that the new expanded indications doesn't adversely affect patient safety.

Therefor, we conclude that the requirements specifications and validation testing show that the modified device is as safe and effective, and performs as well or better as the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1998

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

Re: K980884
Siemens Sevoflurane Vaporizer SV 953
Regulatory Class: II (two)
Product Code: 73 CAD
Dated: June 19, 1998
Received: July 1, 1998

Dear Mr. Simard:

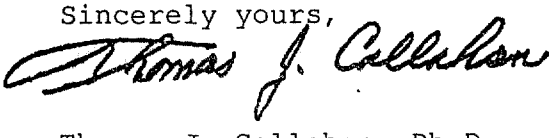
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

Indications for Use Statement:

510(k) Number (if known): K980884

Device Name: Sevoflurane Vaporizer SV953

Indications For Use:

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Substantial Equivalence:

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MRI Compatibility Statement:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)