K092031

Appendix B, Revised 510K Summary

APR 1 8 2010

510(k) Summary K092031

April 7, 2010

Axon Medical Inc.
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Park City, Utah 84098

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Official Contact:	Joseph Orr – President
Proprietary or Trade Name:	Vapor-Clear
Common/Usual Name:	Breathing circuit anesthetic gas scavenger
Primary Classification Name	Gas Scavenging Apparatus
Primary Classification Code:	CBN
Regulation:	868.5430

Predicate Device: K033028
Gas Scavenging Device (product code: CBN)
AneFin 100, Anefin-100 Volatile anesthesia emergence device
Manufacturer: Axon Medical Inc

(Note that the product code for this device in the clearance letter dated July 22, 2005 is CBN)

Device Description: This device uses two anesthetic vapor adsorbent canisters connected to an anesthesia delivery system to prevent unwanted anesthetic vapors emanating from within an anesthesia gas machine from reaching a patient.

Intended Use: To remove unwanted anesthetic gases from the patient breathing circuit

Environment of Use: Operating room, surgical suite, anywhere inhaled volatile anesthetics are administered.

Summary of comparison between device and predicate(s)

Attribute	Vapor-Clear (K092031)	AneFin (K033028)	Comparison
General indications for use	Remove unwanted anesthetic gases	Remove unwanted anesthetic gases	Identical
Specific indications for use	N/A	To speed emergence from volatile inhaled anesthetics and increasing spontaneous breathing through partial rebreathing.	Vapor-Clear is not intended to speed emergence or increase spontaneous breathing.
Patient population	Surgical patients being ventilated by an anesthesia gas machine	Surgical patients being ventilated by an anesthesia gas machine	Identical
Environment of Use	Operating Room	Operating Room	Identical
Rationale for use	To remove unwanted residual anesthetic vapor from the breathing circuit when the vaporizer is turned off.	To remove unwanted residual anesthetic vapor from the breathing circuit when the vaporizer is turned off.	identical
Placement in the anesthesia circuit	Near the anesthesia gas machine ports between the anesthesia gas machine and the breathing circuit hoses.	Between the patient and the breathing circuit wye.	The Vapor-Clear does not rely on rebreathing so there is no need to place the device between the patient and the wye. Vapor-Clear does not include added dead volume.
Change in dead space	None as the device is placed in circuit between the anesthesia gas machine and the breathing circuit hoses Placement is identical to the use of a bacterial filter at the machine end of the circuit	Adds dead space between the wye and the patient. Placement in the breathing circuit is similar to a heat-moisture exchanger	Vapor-Clear does not add dead space. AneFin requires addition of dead space to achieve fast emergence and increase spontaneous breathing.
Equipment	Used with anesthesia gas machine	Used with anesthesia gas machine	Identical

Attribute	Vapor-Clear (K092031)	AneFin (K033028)	Comparison
Anesthetic removal material	Activated charcoal granules	Activated charcoal granules	Identical
Charcoal capacity	0.6" thick, 3 inch diameter. 4.25 cubic inches of charcoal	0.25" thick, 3inch diameter. 1.76 cubic inches of charcoal	Vapor-Clear contains 2.4 times as much charcoal as the AneFin
Anesthetic Removal	>99% of anesthetic gas removed	>95% of anesthetic gas removed	Similar, Vapor-Clear performance is superior
Rebreathing hose	None	Rebreathing hose placed between charcoal canister and breathing circuit wye	The rebreathing hose is used by the AneFin to achieve the additional (specific) intended use. Vapor-Clear does not include a rebreathing hose.
Back pressure	< 2.0 cm H2O at 60 L/min	<1.8cm H2O at 60 L/min	Similar
Internal compliance	7 ml/kPa	14 ml/kPa	Vapor-Clear has less internal compliance
Internal volume	92 ml	183 ml	Vapor-Clear has less internal volume
Anesthetic removal	1300 ml before less than 99% of vapor removed	400 ml before less than 50% of vapor is removed	Vapor-Clear removes more anesthetic gas
Method and timing of installation in breathing circuit	User must break the breathing circuit to install. Placed in breathing circuit when the anesthesia vaporizer has been turned off.	User must break the breathing circuit to install. Placed in breathing circuit when the anesthesia vaporizer has been turned off.	Identical

Summary of Non-Clinical Testing

Test Condition	Test Method	Test Results
Anesthetic adsorption rate	Anesthetic gas removal using an analyzer capable of detection <0.5 ppm	Vapor-Clear scavenges >99.95% of isoflurane at a high flow rate
Scavenging residual vapor from 2 models of modern anesthesia gas machines	Saturate two modern anesthesia gas machines (Draeger Apollo and the Ohmeda Aestiva) with isoflurane for an extended period. Measure the time after the vaporizer has been turned off before the inspired isoflurane falls below 5 parts per million (ppm). Repeat the procedure with and without the Vapor-Clear in the breathing circuit.	Residual vapor exceeds the 5 ppm limit for 78 minutes in the Apollo and 58 minutes in the Aestiva following termination of vapor delivery without the Vapor-Clear. Using, the Vapor- Clear, inspired isoflurane concentration stays below 1 ppm for the duration of the test following termination of vapor delivery. The Vapor-Clear scavenger decreased the concentration of inspiratory isoflurane to less than 1 ppm throughout the tests in both the Draeger Apollo and the Ohmeda Aestiva anesthesia gas machines
Anesthetic removal capacity test	Pass isoflurane through the Vapor-Clear device at a known concentration (2%) and flow rate (5 L/min). Measure the total volume of isoflurane that passes through the device before less than 99% of isoflurane gas is being removed by the device.	A single Vapor-Clear canister removes 1300 ml of isoflurane before a removal rate of less than 99% is observed.
Test adsorption using various anesthetic vapors	Pass anesthetic gas through the device at a known inspired concentration. Measure the concentration entering and exiting the Vapor-Clear device. Repeat the test for each gas (isoflurane, sevoflurane and desflurane)	Greater than 99% of anesthetic is removed regardless of which of the three agents (isoflurane, sevoflurane or desflurane) is used.

Test Condition	Test Method	Test Results
Product life testing	Product containing activated charcoal that has been aged for 71months was tested for initial anesthetic removal and anesthetic removal capacity.	Initial adsorption of >99% was observed. No degradation of anesthetic gas removal capacity was observed when using the aged product.
Environmental testing	The Vapor-Clear device was subjected to mechanical and environmental stresses including shock, vibration, high and low temperature and humidity. The stressed product was then tested for anesthetic removal, leakage and increased back pressure	No change in device performance was observed following the environmental stresses.
Internal volume testing	The internal compressible volume was measured using a direct volume measure. The internal compliance was tested by observing the volume needed to achieve a pressure change in a sealed device.	The internal volume of the device is 92 ml. The internal compliance is 14 ml/kPa.
Burst testing	Increasing pressure was applied to a sealed device in a stepwise fashion until the device burst was observed. The pressure at which a burst was observed was recorded.	The Vapor-Clear burst at a pressure of 70 pounds per square inch.
Back-pressure tests	Added back pressure caused by placing the Vapor-Clear in the breathing circuit was measured per ASTM F 1205	Added back pressure of 0.5 cm H_2O at 30 L/min was observed
Leak test	A pressure of 30 cm H_2O was applied to a sealed device. The flow rate of air into the sealed device was taken as the leak rate per ASTM F 1205	No leak (0.0 ml/min) was detectable.

Testing Summary Statement

The bench testing of the Vapor-Clear device demonstrates that the device is capable of removing unwanted anesthetic gases from the breathing circuit with greater efficiency and capacity than the predicate device. The testing also shows that the Vapor-Clear is capable of scavenging greater than 99% of the residual anesthetic vapors emitted by an anesthesia gas machine after the vaporizer has been turned off. Multiple gas removal testing demonstrated that greater than 99% of anesthetic agent is removed for each anesthetic agent (desflurane, isoflurane and sevoflurane). Testing demonstrated that the activated charcoal used in the device is capable of capturing a volume of anesthetic gas that is well beyond what is emitted by an anesthesia gas machine after the vaporizer has been turned off. Testing using aged activated charcoal granules demonstrate that the device will perform as specified throughout the product lifetime. Environmental and mechanical testing demonstrates that the leak, back pressure and internal volume of the device are sufficiently small that installation of the device will not interfere with delivery of mechanical ventilation during an anesthetic and that the device is sufficiently rugged to withstand the rigors of shipping and storage.

These tests demonstrate that the subject device (Vapor-Clear) is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Joseph Orr
President
Axon Medical, Incorporated
2645 Sackett Drive
Park City, Utah 84098

APR 1 3 2010

Re: K092031
Trade/Device Name: Vapor-Clear
Regulation Number: 21CFR 868.5430
Regulation Name: Gas-Scavenging Apparatus
Regulatory Class: II
Product Code: CBN
Dated: April 5, 2010
Received: April 8, 2010

Dear Dr. Orr:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K092031

Device Name: Vapor-Clear

Indications for Use: To remove unwanted anesthetic gases from the patient breathing circuit

Intended patient population: Surgical patients being ventilated by an anesthesia gas machine.

Environment of Use: Operating room, surgical suite, anywhere inhaled volatile anesthetics are administered.

Prescription Use: XX OR Over-The-Counter Use_____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

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sion of Anesthesiology, General Hospital
ection Control, Dental Devices

(k) Number: K092031