DE NOVO CLASSIFICATION REQUEST FOR
AIRPURGE SYSTEM

REGULATORY INFORMATION

FDA identifies this generic type of device as:

INTRAVASCULAR ADMINISTRATION SET, AUTOMATED AIR REMOVAL SYSTEM
An intravascular administration set, automated air removal system is a prescription device used to detect and automatically remove air from an intravascular administration set with minimal to no interruption in the flow of the intravascular fluid. The device may include an air identification mechanism, software, an air removal mechanism, tubing, apparatus to collect removed air, and safety control mechanisms to address hazardous situations.

NEW REGULATION NUMBER: 21 CFR 880.5445

CLASSIFICATION: Class II

PRODUCT CODE: OKL

BACKGROUND

DEVICE NAME: AirPurge System

SUBMISSION NUMBER: K080644

DATE OF DE NOVO: October 29, 2008

CONTACT: Anesthesia Safety Products, LLC
155-M New Boston Street, Suite 127
Woburn, Massachusetts 01801

REQUESTER'S RECOMMENDED CLASSIFICATION: Class II

INDICATIONS FOR USE

The AirPurge™ System is intended for detection and automatic removal of air in intravenous (I.V.) lines during administration of intravenous solutions, blood and blood products. It is indicated for use in the Operating Room and post anesthesia care areas. The AirPurge™ System is placed distal to I.V. bags using gravity feed or pressure, and may be used with or without fluid warmers.

LIMITATIONS
Prescription use only

Limitations on device use are also achieved through the following statements included in the Instructions for Use Manual:

Warning: The safety and effectiveness of the AirPurge System has not been evaluated for use with active infusion devices, such as drug infusion pumps and hemodialysis systems.

Caution: The AirPurge™ System is not a replacement for human vigilance. I.V. lines should always be monitored for signs of entrapped air.

Caution: All Users must be trained; training is required for the safe and proper use of the AirPurge™ System.

Caution: The AirPurge™ System is not a replacement for the proper handling of I.V. setups.

Air Identification and Removal Specifications:

1. The device's air identification and removal response time.

Response Time
Less than 60 milliseconds

2. The device's minimum air volume identification sensitivity

Minimum Detectable Air Volume
25 microliter

3. The minimum and maximum flow rates at which the device is capable of reliably detecting and removing air.

Flow Rate Specifications	
Minimum Flow Rate	1 mL/hr
Maximum Flow Rate	600 mL/hr

4. Quantification of any fluid loss during device air removal operations as a function of flow rate.

Flow Rate	**Fluid Volume Loss per Purge**
600mL/min	10 mL
300mL/hr	0.1 mL

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Airpurge System (AirPurge) is intended to detect and automatically remove air from an IV infusion line.

Figure-1a, Disposable Unit **Figure-1b, Control Unit**

Airpurge consists of two main components, the control unit and the disposable unit. The disposable unit (Figure-1a) contains the system fluid path and is a sterile, single-use component. This disposable unit is loaded onto the control unit (Figure-1b). The door of the control unit is then closed. Once the device is connected to the infusion line and primed, it uses an ultrasonic sensor to detect air in the infusion line. When air is detected, the device system closes the patient line and diverts the fluid flow to the waste collection bag. A second ultrasonic sensor detects when the air has been removed from the IV line and causes the controller to return the infusion flow back to the patient.

SUMMARY OF NONCLINICAL/BENCH STUDIES

A series of non-clinical studies, summarized in Table 1, were conducted to verify that the AirPurge System performs as intended. These particular studies were chosen because of their relationship to demonstrating that the AirPurge System device hazards have been adequately addressed. The hazards are dependent on the context of use (e.g., indicated uses, use environments and users) and the device specific design.

Table 1 - AirPurge System Nonclinical Studies

<table>
<tr><th>Test</th><th>Purpose</th><th>Acceptance Criteria</th><th>Results</th></tr>
<tr><td colspan="2">(b)(4) Trade Secret Formula & Process</td><td></td><td>Pass</td></tr>
<tr><td>Component Reliability Assessment</td><td colspan="2">(b)(4) Trade Secret Formula & Process</td><td>Pass</td></tr>
<tr><td>Flow Rate</td><td colspan="2"></td><td>Pass</td></tr>
<tr><td>Fluid Loss</td><td>Characterize the fluid loss per air removal cycle as a function of flow rate. Results included in labeling.</td><td>Characterization Test
<table><tr><th>Flow Rate</th><th>Fluid Volume Loss per Purge</th></tr><tr><td>600mL/min</td><td>10 mL</td></tr><tr><td>300mL/hr</td><td>0.1 mL</td></tr></table></td><td></td></tr>
<tr><td>Limits of Air Detection</td><td>Characterize the minimum air volume detection and removal capability of the device.</td><td>Characterization Test
<table><tr><th>Minimum Detectable Air Volume</th></tr><tr><td>25 microliter</td></tr></table></td><td></td></tr>
<tr><td>Safety Controls</td><td colspan="2">(b)(4) Trade Secret Formula & Process</td><td>Pass</td></tr>
</table>

	(b)(4) Trade Secret Formula & Process		
Fluid Ingress			Pass
Biocompatibility	Demonstrate that contamination hazards caused by non-biocompatible device components are adequately addressed.	See biocompatibility review summary	Pass
Sterilization	Demonstrate that contamination hazards caused by non-sterile device components are adequately addressed.	See sterilization review summary	Pass
Shelf Life	Support the labeled (b)(4) TS Formula shelf life for disposable units. (b)(4) Trade Secret Formula & Process	Demonstrate sterile barrier packaging integrity and functional performance.	Pass
(b)(4) Trade Secret Formula & Process			Pass
Electromagnetic Compatibility and Electrical	Demonstrate that electrical hazards are adequately addressed.	Demonstrate conformance to relevant aspects of	Pass

Safety		the ~~following~~ standards: (b)(4) Trade Secret Formula & Process Appropriate information is included in the AirPurge System instructions for use..	
Software	Demonstrate that the software is adequately verified and validated for its intended use.	See software review summary	Pass
Human Factors	Demonstrate that the design of the AirPurge System has adequately addressed potential use error hazards that may result in patient harm.	See human factors review summary	Pass

BIOCOMPATIBILITY/MATERIALS

The biocompatibility and hemocompatibility (Table 2) testing included those tests recommended by FDA memorandum G95-1 entitled "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing' for externally communicating devices, prolonged duration, blood path, indirect devices.

The results of this testing demonstrated the disposable components of the AirPurge System is biocompatible when used as intended.

Table 2 - Biocompatibility Tests

Test	Method	Results
(b)(4) Trade Secret Formula & Process		Pass
		Pass
		Pass
		Pass
		Pass
		Pass
		Pass
		Pass

STERILITY

Sterilization specifications (Table 3) were evaluated in a similar manner as IV administration sets.

Table 3 - Sterilization Data

Sterilization Information	Methods / Results
Sterilization Method	Ethylene Oxide
Sterilant Residuals	(b)(4) Trade Secret Formula & Process
Sterilization Validation Method	ANSI/AAMI/ISO 11135
Sterility assurance level (SAL):	10^{-6}
Pyrogenicity Evaluation	(b)(4) Trade Secret Formula & Process

	Pass
Sterile Barrier Packaging	The sterile components are packaged in a Tyvek/Poly pouch.

SOFTWARE

Software for the device consisted of proprietary software. The device software was reviewed and the provided documentation (Table 4) was found adequate and consistent with a 'MAJOR' Level of Concern , as defined in FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued on May 11, 2005.

FDA's review of the documentation determined that the documentation is complete and deemed acceptable.

Table 4 - Software Documentation

Level of Concern: Major	
	Acceptable
Software description:	Yes
Device Hazard Analysis:	Yes
Software Requirements Specifications:	Yes
Architecture Design Chart:	Yes
Design Specifications:	Yes
Traceability Analysis/Matrix:	Yes
Development:	Yes
Verification & Validation Testing:	Yes
Revision level history:	Yes
Unresolved anomalies:	Yes

HUMAN FACTORS

A human factors study was conducted (b)(4) Trade Secret Formula & Process

A final human factors study report was reviewed for the following information:

(b)(4) Trade Secret Formula & Process

(b)(4) Trade Secret Formula & Process

Based on the results of the study, Anesthesia Safety Products will require that all users must be trained on the proper use of the AirPurge System (b)(4) Trade Secret Formula & Process

A user task analysis identified the following tasks necessary for use of the device. (b)(4) Trade Secret Formula & Process

(b)(4) Trade Secret Formula & Process

Specific use errors observed included:

(b)(4) Trade Secret Formula & Process

(b)(4) Trade Secret Formula & Process

LABELING

In addition to meeting the general labeling controls for prescription devices under 21 CFR 801.109, the following specific labeling controls, as identified in Table 5, are included and necessary to reasonably ensure safety and effectiveness of the AirPurge System:

Table 5 - Labeling Controls

Labeling Control	AirPurge System Data
The device's air identification and removal response time.	60 milliseconds
The device's minimum air volume identification sensitivity	25 microliters

The minimum and maximum flow rates at which the device is capable of reliably detecting and removing air.	Minimum: 1 mL/hr Maximum: 600 mL/min
Quantification of any fluid loss during device air removal operations as a function of flow rate.	**Flow Rate** / **Fluid Volume Loss per Purge** 600mL/min / 10 mL 300mL/hr / 0.1 mL

RISKS TO HEALTH

Table 6 identifies the risks to health that may be associated with use of an intravascular administration set automated air removal system and the measures necessary to mitigate these risks.

Table 6 - Risks to Health and Mitigation Measures

Risk	Mitigation
Embolus	Hazard Argument Software Electromagnetic Compatibility Human Factors Labeling Non-clinical Performance Testing
Infusion delivery error	Hazard Argument Software Electromagnetic Compatibility Human Factors Labeling Non-clinical Performance Testing
Electric Shock	Hazard Argument Electrical Safety Electromagnetic Compatibility
Adverse Tissue Reaction	Hazard Argument Biocompatibility
Infection	Sterilization Shelf Life

SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the AirPurge System is subject to the following special controls:

(1) Provide an argument demonstrating that all reasonably foreseeable hazards have been adequately addressed with respect to the persons for whose use the device is represented or intended and the conditions of use for the device, which includes the following:
   (i) Description of the device indications for use, design and technology, use environments, and users in sufficient detail to determine that the device complies with all special controls.

(ii) Demonstrate that controls are implemented to address device system hazards and their causes.
(iii) Include a justification supporting the acceptability criteria for each hazard control.
(iv) A traceability analysis demonstrating that all credible hazards have at least one corresponding control and that all controls have been verified and validated in the final device design.

(2) Appropriate software verification, validation, and hazard analysis must be performed.
(3) The device parts that directly or indirectly contact the patient must be demonstrated to be biocompatible.
(4) Performance data must demonstrate the sterility of fluid path contacting components and the shelf-life of these components.
(5) The device must be designed and tested for electrical safety and electromagnetic compatibility (EMC).
(6) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
    (i) Device system and component reliability testing must be conducted.
    (ii) Fluid ingress protection testing must be conducted.
    (iii) Testing of safety controls must be performed to demonstrate adequate mitigation of hazardous situations, including sensor failure, flow control failure, improper device position, device malfunction, infusion delivery error, and release of air to the patient.
(7) A human factors validation study must demonstrate that use hazards are adequately addressed.
(8) The labeling must include the following:
    (i) The device's air identification and removal response time.
    (ii) The device's minimum air volume identification sensitivity.
    (iii) The minimum and maximum flow rates at which the device is capable of reliably detecting and removing air.
    (iv) Quantification of any fluid loss during device air removal operations as a function of flow rate.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

BENEFIT/RISK DETERMINATION

(b)(4) Trade Secret Formula & Process

(b)(4) Trade Secret Formula & Process

The primary review criteria used to evaluate the device are the device's capability to detect and remove air from an infusion line. The characteristics evaluated are

- Air detection and removal response time
- Minimum air volume identification sensitivity
- Minimum and Maximum flow rates at which the device is capable of reliably detecting and removing air
- Quantification of fluid loss during air removal operations as a function of flow rate

(b)(4) Trade Secret Formula & Process

Many devices that include air detection mechanisms stop the drug delivery when the air is detected. The expected benefit of the Airpurge device is the prevention of air infusion coupled with the minimization of drug delivery interruptions.

In conclusion, given the available information above, the data support that for detection and automatic removal of air in intravenous (I.V.) lines during administration of intravenous solutions, blood and blood products, the probable benefits outweigh the probable risks for the AirPurge System. The device provides benefits and the risks can be mitigated by (b)(4) Trade Secret Formula & Process

CONCLUSION

The *de novo* for the AirPurge System is granted and the device is classified under the following:

Product Code: OKL
Device Type: Intravascular Administration Set, Automated Air Removal System
Class: II
Regulation: 21 CFR 880.5445