



Food and Drug Administration  
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March 4, 2014

Ihsan A. Haddad  
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Re: K080644  
AirPurge System  
Evaluation of Automatic Class III Designation – *De Novo* Request  
Regulation Number: 21 CFR 880.5445  
Regulation Name: Intravascular Administration Set, Automated Air Removal System  
Regulatory Classification: Class II  
Product Code: OKL  
Dated: October 28, 2008  
Received: October 29, 2008

Dear Mr. Haddad:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the AirPurge System, a prescription device under 21 CFR Part 801.109 that is indicated for detection and automatic removal of air in intravascular (IV) 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. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the AirPurge System, and substantially equivalent devices of this generic type, into class II under the generic name, Intravascular Administration Set, Automated Air Removal System.

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.

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified

under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on October 23, 2008 automatically classifying the AirPurge System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On October 29, 2008, FDA received your *de novo* requesting classification of the AirPurge System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the AirPurge System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the AirPurge System indicated for detection and automatic removal of air in IV lines during administration of blood, blood products and intravenous solution can be classified in class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures with the device type are summarized in Table 1.

**Table 1 - Identified Risks to Health and Mitigation Measures**

Identified Risk	Mitigation Measures
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
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In combination with the general controls of the FD&C Act, the Intravascular Administration Set, Automated Air Removal 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.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Intravascular Administration Set, Automated Air Removal System they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request 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.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact CDR Alan M. Stevens at 301-796-6294.

Sincerely yours,

**Jonette R. Foy -S**

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