

Guidance for Industry and FDA

**Guidance for Extracorporeal Blood
Circuit Defoamer 510(k)
Submissions**

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Catherine Wentz, Center for Devices and Radiological Health, 9200 Corporate Boulevard, HFZ-450, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Catherine Wentz at (301) 443-8243.

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Guidance¹ for Extracorporeal Blood Circuit Defoamer 510(k) Submissions

Introduction:

This guidance document describes a means by which cardiopulmonary bypass defoamer devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate cardiopulmonary bypass defoamer device should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

This guidance document has been developed as a special control to support a change in classification from class III to class II. It identifies relevant material on preclinical studies and labeling to include in a 510(k) premarket notification application. We intend it be used in conjunction with other identified special controls, Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, dated May 1, 1995, and 510(k) Sterility Review Guidance and Revision of 11/18/94. All FDA requirements regarding premarket notification submissions are not repeated in this document.

Scope:

An extracorporeal circuit blood defoamer (21 CFR 870.4230) is a filter device used to remove gas bubbles from the blood for up to six hours. It may be used on the arterial side of a extracorporeal circuit distal to the oxygenator during cardiopulmonary bypass surgery. It may also be used on the venous side before the oxygenator during cardiopulmonary bypass procedures, and in open and closed auto transfusion procedures. The device when used on the venous side is usually an integral part of the cardiopulmonary bypass blood reservoir (21 CFR 870.4400).

¹ This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

| RISKS TO HEALTH | CONTROLS |
|--|---|
| <p>1. Thromboembolism, Embolism complications, Blood damage</p> | <p><u>Blood Studies</u>: Evaluate hemolysis and cell depletion; blood component counts, blood component functionality; e.g., platelet function over a 6 hour circulation period for the subject, predicate and dynamic control circuits. Use circuits at the maximum, labeled flow rate.</p> <p><u>Visual Inspection</u>: Gross inspection for thromboemboli.</p> |
| <p>2. Inadequate blood flow, Excessive pressure gradients, Structural integrity</p> | <p><u>Pressure testing</u>: Include burst pressure, sustained/static pressure at 1.5 times the maximum anticipated pressure for intended use for 6 hours and pressure drop to steady state at highest rated flow rate. Observe for leaks, tears, and structural integrity. Use blood or a blood analog as the testing medium.</p> |
| <p>3. Structural damage under intended use conditions</p> | <p><u>Leak testing</u>: Assess mechanical integrity by testing under static pressure conditions as noted in pressure testing above. Test and state the pull strength required to separate the connections.</p> |
| <p>4. Gaseous emboli</p> | <p><u>Defoaming testing</u>: Demonstrate the ability of the defoamer to eliminate foam as indicated in the labeling, at the flow rates indicated in the labeling, e.g., 0.5, 1.0, and 1.5 liters/min. Describe the acceptance criteria, e.g., the complete absence of foam in the reservoir.</p> <p>INCLUDE A BUBBLE DETECTOR AS A CIRCUIT COMPONENT.</p> |
| <p>5. Excessive pressure gradients; i.e., blood damage, inadequate blood flow</p> | <p><u>Flow rate capacity</u>: Determine the flow rate limitation(s) to assure safe and effective performance.</p> |

| RISKS TO HEALTH | CONTROLS |
|---|---|
| <p>6. User error</p> | <p><u>Labeling</u>: Include clear, concise instructions for use. Describe the human factors review e.g., inclusion of a troubleshooting guide, easy formatting of instructions for use, etc.</p> <p>Provide rated filtration efficiency, flow rate and duration of use (e.g., 6 hours), and other pertinent information obtained through performance testing to facilitate correct use of the device. THE USE OF A BUBBLE DETECTOR MUST BE INCLUDED AS A CIRCUIT COMPONENT.</p> |
| <p>7. Blood incompatibility</p> | <p><u>Biocompatibility testing</u>: Perform testing recommended in the FDA guidance on ISO 10993: <u>Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing</u>, dated May 1, 1995 to assure that the materials used are non-toxic for the intended use. Include sensitization, pyrogenicity, acute systemic toxicity, mutagenicity, cytotoxicity, irritation, and hemocompatibility/hemolysis testing.</p> |
| <p>8. Incompatibility of the product when exposed to circulating blood; and infection.</p> | <p><u>Sterilization</u>: Perform sterilization validation to ensure that the sterilization process is capable of providing a Sterility Assurance Limit (SAL) of 10^{-6}. Perform biological, pyrogen, and bioburden testing to ensure acceptable limits of biological contaminants.</p> |
| <p>9. Insufficient device performance, material incompatibility, and lack of sterilization over a period of time</p> | <p><u>Shelf-life</u>: Validate the package shelf-life to ensure that the device will remain sterile for the period of time specified on the label:</p> <p>Test simulated or real shipment and handling conditions: dropping, vibration, stacking, temperature, humidity, and atmospheric pressure extremes followed by device functionality testing.</p> <p>Study real or accelerated aging: if accelerated aging is used, follow-up with real-time testing to verify the accelerated results.</p> <p>Study package integrity and barrier property assessment: use validated physical or microbial-based methods.</p> |