

ATTACHMENT 3

REVISED GUIDANCE FOR EXTRACORPOREAL BLOOD CIRCUIT DEFOAMER 510(k) SUBMISSIONS: CLEAN COPY

Guidance for Industry and FDA

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

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**U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Circulatory Support and Prosthetic Devices Branch
Division of Cardiovascular Respiratory and Neurology Devices
Office of Device Evaluation**

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.

Additional Copies

World Wide Web/CDRH/home page:
<http://www.fda.gov/cdrh/ode/1632.pdf> or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1632 when prompted for the document shelf number.

RISK TO HEALTH	CONTROLS
1. Thromboembolism, Embolism complications, Blood damage	<p><u>Blood Studies</u>: Evaluate hemolysis, white blood cell, and platelet depletion over the labeled life of the device. Compare the subject device with predicate device at the maximum rated flow rate.</p> <p><u>Visual Inspection</u>: Gross inspection for thromboemboli.</p>
2. Inadequate blood flow, Excessive pressure gradients, Structural integrity	<p><u>Pressure Testing</u>: Perform burst pressure for test devices using sustained static pressure at 1.5 times the maximum anticipated pressure for intended use over the labeled life of the device. Observe for leaks, tears, and structural integrity. Use water or saline as the test medium.</p> <p><u>Pressure Drop</u>: Perform pressure drop testing to steady state at highest rated flow rate. Use blood or a blood analog as the testing medium.</p>
3. Structural damage under intended use conditions	<p><u>Leak Testing</u>: Assess mechanical integrity by testing under static pressure conditions as noted in pressure testing above.</p>
4. Gaseous emboli	<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. RECOMMEND USE OF A BUBBLE DETECTOR AS A CIRCUIT COMPONENT.</p> <p><u>Labeling</u>: Recommend use of Bypass Checklist. Recommend use of an appropriate filter.</p>
5. Excessive pressure gradients; i.e., blood damage, inadequate blood flow	<p><u>Labeling</u>: Recommend use of bypass loop or change-out procedure.</p>

RISK TO HEALTH	CONTROLS
6. User error	<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 flow rate and duration of use (e.g., 6 hours), and other pertinent information obtained through performance testing. THE USE OF A BUBBLE DETECTOR IS RECOMMENDED AS A CIRCUIT COMPONENT.</p>
7. Blood incompatibility	<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>
8. Incompatibility of the product when exposed to circulating blood; and infection	<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 indicators (as applicable), pyrogen, and bioburden testing to ensure acceptable limits of biological contaminants.</p>
9. Insufficient device performance, material incompatibility, and lack of sterility over a period of time	<p><u>Shelf-Life</u>: Study and submit real or accelerated aging. If accelerated aging results are submitted in the 510(k), the sponsor will make an assessment as to the need for follow-up with real-time results.</p> <p>Validate the package shelf-life to ensure that the device will remain sterile for the period of time specified on the label.</p> <p>Include package integrity and barrier property assessment using validated physical or microbial-based methods.</p> <p>Include a statement in the 510(k)</p>

RISK TO HEALTH	CONTROLS
	indicating that simulated or real shipment and handling conditions (dropping, vibration, stacking, temperature, and humidity) evaluations followed by device functionality testing will be completed before commercial release.