

**K230987 FlowStar Analog Mixer Flowmeter**Sep 14, 2023  
161 days to decisionK230987 · Product code: **BZR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k230987/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixer, Breathing Gases, Anesthesia Inhalation (BZR)
Date received	Apr 6, 2023
Decision date	Sep 14, 2023
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Baldus Sedation GmbH &amp; Co. KG</b>
Location	Bendorf, DE
Contact	Lisa Baldus
510(k) history	2 submissions · 2 cleared · 2023-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Kamm &amp; Associates</b>
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230987/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 25, 2026