

K222794 FlowStar Touch Digital Mixer FlowmeterJul 28, 2023
315 days to decisionK222794 · Product code: **BZR** · Anesthesiology
Source: <https://www.510kdatabase.net/k222794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixer, Breathing Gases, Anesthesia Inhalation (BZR)
Date received	Sep 16, 2022
Decision date	Jul 28, 2023
Days to decision	315 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Kamm & Associates
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)

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