

K251631 The BAG manual resuscitator and accessoriesNov 24, 2025
180 days to decisionK251631 · Product code: **BTM** · AnesthesiologySource: <https://www.510kdatabase.net/k251631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	May 28, 2025
Decision date	Nov 24, 2025
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Laerdal Medical AS
Location	Stavanger, NO
Contact	Claudia Pajares Ibanez
510(k) history	5 submissions · 5 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	MED Institute
Contact	Daniel Dillon

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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