

K243861 butterflyBVMApr 25, 2025
130 days to decisionK243861 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k243861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Dec 16, 2024
Decision date	Apr 25, 2025
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Compact Medical, Inc.
Location	Indianapolis, IN, US
Contact	Jonathan Merrell
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243861/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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