

K242485 EveryWareMay 20, 2025
272 days to decisionK242485 · Product code: **MOD** · AnesthesiologySource: <https://www.510kdatabase.net/k242485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory To Continuous Ventilator (respirator) (MOD)
Date received	Aug 21, 2024
Decision date	May 20, 2025
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Breas Medical AB
Location	Molnlycke, Vastra Gotaland, SE
Contact	Ivan Liljegren
510(k) history	15 submissions · 15 cleared · 2006-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242485/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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