

K242438 ClearoMay 16, 2025
273 days to decisionK242438 · Product code: **NHJ** · Anesthesiology
Source: <https://www.510kdatabase.net/k242438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Positive Pressure Breathing, Intermittent (NHJ)
Date received	Aug 16, 2024
Decision date	May 16, 2025
Days to decision	273 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/k242438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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