

K243583 F&P Nova Nasal MaskJun 18, 2025
210 days to decisionK243583 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k243583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Nov 20, 2024
Decision date	Jun 18, 2025
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fisher & Paykel Healthcare Limited
Location	Auckland, NZ
Contact	Reena Daken
510(k) history	8 submissions · 8 cleared · 2012-2025

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