

K121597 ESON NASAL MASKOct 2, 2012
124 days to decisionK121597 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k121597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	May 31, 2012
Decision date	Oct 2, 2012
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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