

K130328 F&P SIMPLUS FULL FACE MASKJun 5, 2013
114 days to decisionK130328 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k130328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 11, 2013
Decision date	Jun 5, 2013
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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