

**K223696 F&P Solo Mask Range**May 17, 2023  
159 days to decisionK223696 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k223696/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 9, 2022
Decision date	May 17, 2023
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fisher &amp;Paykel Healthcare , Ltd.</b>
Location	Auckland, New Zealand, NZ
Contact	Reena Daken
Website	<a href="https://www.fphcare.com/">https://www.fphcare.com/</a>
510(k) history	70 submissions · 70 cleared · 1988-2025

Fisher &Paykel Healthcare, Ltd. is a medical device manufacturer based in Auckland, New Zealand. The company has driven innovation in healthcare technologies for over 50 years. Fisher &Paykel Healthcare has received FDA 510(k) clearances from total submissions since 1988. The company specializes in Anesthesiology devices, which represent 91% of its regulatory submissions. The latest clearance was granted in 2025, confirming active ongoing development. Recent cleared devices include high-flow nasal therapy systems, noninvasive ventilation masks, and respiratory support int...