

**K190713 F&P Vitera Mask Full Face A Model (Small, Medium, Large), F&P Vitera Mask Full Face Sleep Lab Model (Small, Medium, Large)**Oct 11, 2019  
206 days to decisionK190713 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k190713/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Mar 19, 2019
Decision date	Oct 11, 2019
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fisher &amp;Paykel Healthcare , Ltd.</b>
Location	Auckland, New Zealand, NZ
Contact	Masar Mohammad
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...