

**K252173 F&P OptiNIV Hospital Vented Full Face Mask  
Compatible with Single-limb Circuits – Size A (ONIV117A)**

Sep 10, 2025  
61 days to decision

K252173 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k252173/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jul 11, 2025
Decision date	Sep 10, 2025
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	F&P OptiNIV Hospital Vented Full Face Mask Compatible with Single-limb Circuits – Size B (ONIV117B); F&P OptiNIV Hospital Vented Full Face Mask Compatible with Single-limb Circuits – Size C (ONIV117C); F&P OptiNIV ONIV117-F Hospital Vented Full Face Mask with optional Expiratory Filter Compatible with Single-limb Circuits - Size A (ONIV117A-F); F&P OptiNIV ONIV117-F Hospital Vented Full

**APPLICANT**

---

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...