

**K083122 HOSPITAL FULL FACE MASK NON VENTED, MODEL:
RT041**Mar 4, 2009
133 days to decisionK083122 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k083122/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Oct 22, 2008
Decision date	Mar 4, 2009
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fisher &Paykel Healthcare , Ltd.
Location	Auckland, New Zealand, NZ
Contact	STEPHANIE COSTE
Website	https://www.fphcare.com/
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...

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Device record: <https://www.510kdatabase.net/k083122/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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