

**K173060 F&P Nivairo™ RT046 Non-Vented Hospital Full Face Mask, Standard Elbow Version**Jan 25, 2018  
119 days to decisionK173060 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k173060/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Sep 28, 2017
Decision date	Jan 25, 2018
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fisher and Paykel Healthcare Limited</b>
Location	Auckland, NZ
Contact	Ashley Nguyen
510(k) history	3 submissions · 3 cleared · 2017-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173060/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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