

**K170367 Nivairo RT045 Non-Vented Hospital Full Face Mask  
Anti-Asphyxiation Valve - Large, Nivairo RT045 Non-Vented  
Hospital Full Face Mask Anti-Asphyxiation Valve - Medium,  
Nivairo RT045 Non-Vented Hospital Full Face Mask Anti-  
Asphyxiation Valve - Small, Nivairo RT045 Non-Vented Hospital  
Full Face Mask Anti-Asphyxiation Valve - Extra Small**

Aug 24, 2017  
199 days to decision

K170367 · Product code: MNT · Anesthesiology  
Source: <https://www.510kdatabase.net/k170367/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use (MNT)
Date received	Feb 6, 2017
Decision date	Aug 24, 2017
Days to decision	199 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	Danica Tung
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/k170367/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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