

**K191624 F&P Nivairo RT047 Vented Hospital Full Face Mask,  
Anti-Asphyxiation Valve Version**Mar 9, 2020  
265 days to decisionK191624 · Product code: **MNT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k191624/>**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         | Jun 18, 2019                                                            |
| Decision date         | Mar 9, 2020                                                             |
| Days to decision      | 265 days                                                                |
| Third-party review    | No                                                                      |
| Summary / Statement   | Summary                                                                 |

**APPLICANT**

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|----------------|-----------------------------------------------|
| Company        | <b>Fisher &amp; Paykel Healthcare Limited</b> |
| Location       | Auckland, NZ                                  |
| Contact        | Nicholas Yap                                  |
| 510(k) history | 8 submissions · 8 cleared · 2012-2025         |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191624/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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