

**K200089 F&P Evora Nasal Mask Nasal A Model (Small, Medium, Large, Wide), F&P Evora Nasal Mask Nasal Fit Pack/ SML (Small/Medium/Large) A Model, F&P Evora Nasal Mask Nasal Sleep Lab (Small, Medium, Large, Wide), F&P Evora Nasal Mask Nasal Fit Pack / SML (Small/Medium/Large) Sleep Lab Model**

Jun 2, 2020  
139 days to decision

K200089 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k200089/>

**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received         | Jan 15, 2020                                  |
| Decision date         | Jun 2, 2020                                   |
| Days to decision      | 139 days                                      |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|----------------|---|
| 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...