

**K153505 F&P Eson 2 Nasal Mask**Sep 20, 2016  
288 days to decisionK153505 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k153505/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 7, 2015
Decision date	Sep 20, 2016
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153505/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026