

K251615 Aerogen Pro-X1 Controller SystemSep 2, 2025
98 days to decisionK251615 · Product code: **SFP** · AnesthesiologySource: <https://www.510kdatabase.net/k251615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator-compatible Nebulizer (SFP)
Date received	May 27, 2025
Decision date	Sep 2, 2025
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aerogen, Ltd.
Location	Galway, IE
Contact	Thelma Marley
510(k) history	5 submissions · 5 cleared · 2011-2025

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