

K232507 Aerogen®Solo Nebulizer SystemMay 10, 2024
266 days to decisionK232507 · Product code: **CAF** · AnesthesiologySource: <https://www.510kdatabase.net/k232507/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nebulizer (direct Patient Interface) (CAF) |
| Date received | Aug 18, 2023 |
| Decision date | May 10, 2024 |
| Days to decision | 266 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 |

REGULATORY CONSULTANT

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|-----------------|---------------------------------------|
| Consulting firm | Aerogen Ltd. C/O Promedic, LLC |
| Contact | Paul Dryden |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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