

**K253030 Capnostream™35 Portable Respiratory Monitor
(PM35MN)**May 1, 2026
224 days to decisionK253030 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k253030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Sep 19, 2025
Decision date	May 1, 2026
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Shannon Ryan
510(k) history	88 submissions · 85 cleared · 2010-2026

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