

K253119 CoSense ETCO MonitorMay 29, 2026
247 days to decisionK253119 · Product code: **CCJ** · Anesthesiology
Source: <https://www.510kdatabase.net/k253119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-monoxide, Gaseous-phase (CCJ)
Date received	Sep 24, 2025
Decision date	May 29, 2026
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Capnia, Inc.
Location	Palo Alto, CA, US
Contact	Ed Baumann
510(k) history	4 submissions · 4 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Rob Packard

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

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