

K261633 VisuBreath

Jul 14, 2026
57 days to decision

K261633 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k261633/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	May 18, 2026
Decision date	Jul 14, 2026
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Affirm Medical Technologies II, LLC
Location	Piedmont, CA, US
Contact	Brian Cain
510(k) history	1 submissions · 1 cleared · 2026-2026