

K200594 Capnostream 35 Portable Respiratory MonitorApr 27, 2020
52 days to decisionK200594 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k200594/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Mar 6, 2020
Decision date	Apr 27, 2020
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oridion Medical 1987 , Ltd.
Location	Jerusalem, IL
Contact	Lital David
510(k) history	19 submissions · 19 cleared · 2001-2020

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Jonathan Kahan

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

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