

**K201590 EMMA Capnograph**Mar 29, 2021  
290 days to decisionK201590 · Product code: **CCK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k201590/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Jun 12, 2020
Decision date	Mar 29, 2021
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Masimo Corporation</b>
Location	Irvine, CA, US
Contact	Katelynn Kirby
Website	<a href="http://www.masimo.com/">http://www.masimo.com/</a>
510(k) history	84 submissions · 82 cleared · 2004-2025

Masimo Corporation is an American health technology and consumer electronics company headquartered in Irvine, California. The company develops patient monitoring devices, non-invasive sensors, and related software platforms for hospital and home settings. Masimo has received FDA 510(k) clearances from total submissions since its first clearance in 2004. The company's regulatory focus centers on Anesthesiology devices, which represent 74% of submissions. Latest clearance activity in 2025 demonstrates continued regulatory engagement. Recent cleared devices span Anesthesiolo...

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