

**K103604 ISA CO2, ISA AX+, ISA OR+**Apr 6, 2011  
118 days to decisionK103604 · Product code: **CCK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k103604/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Dec 9, 2010
Decision date	Apr 6, 2011
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Phasein AB</b>
Location	Madison, WI, US
Contact	DAVID WEISSBURG
510(k) history	5 submissions · 5 cleared · 2007-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103604/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 24, 2026