

K123043 IRMA C02 MODEL 200101Oct 25, 2012
27 days to decisionK123043 · Product code: **CCK** · AnesthesiologySource: <https://www.510kdatabase.net/k123043/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK) |
| Date received | Sep 28, 2012 |
| Decision date | Oct 25, 2012 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | IRMA AX 200601 |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123043/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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