

K092135 MODIFICATION TO IVENT 101Nov 23, 2009
131 days to decisionK092135 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k092135/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Ventilator, Continuous, Facility Use (CBK) |
| Date received | Jul 15, 2009 |
| Decision date | Nov 23, 2009 |
| Days to decision | 131 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Versamed Medical Systems , Ltd. |
| Location | Madison, WI, US |
| Contact | ADRIANNE LENZ |
| 510(k) history | 2 submissions · 2 cleared · 2009-2012 |

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