

**K981668 SMARTVENT 201 PORTABLE VENTILATOR**Apr 7, 1999  
331 days to decisionK981668 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k981668/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	May 11, 1998
Decision date	Apr 7, 1999
Days to decision	331 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Versamed , Ltd.</b>
Location	Tel-Aviv, IL
Contact	SHOSHANA FRIEDMAN
510(k) history	3 submissions · 3 cleared · 1999-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981668/> 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 25, 2026