

**K080439 SANDMAN INFO WITHOUT HUMIDIFIER/ SANDMAN  
AUTO WITHOUT HUMIDIFIER, MODEL M-114801-114802-US**May 16, 2008  
87 days to decisionK080439 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k080439/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 19, 2008
Decision date	May 16, 2008
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary
Other names	SANDMAN INFO WITH INTERGRATE

**APPLICANT**

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Company	<b>Mallinckrodt Developpement France</b>
Location	Villers-Les-Nancy Cedex, FR
Contact	TINA DREILING
510(k) history	7 submissions · 7 cleared · 2000-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080439/> 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