

**K853971 REGULATOR-INHALATOR SYSTEM**Dec 9, 1985  
74 days to decisionK853971 · Product code: **BTL** · AnesthesiologySource: <https://www.510kdatabase.net/k853971/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Powered (resuscitator) (BTL)
Date received	Sep 26, 1985
Decision date	Dec 9, 1985
Days to decision	74 days
Third-party review	No

**APPLICANT**

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Company	<b>Stephenson Industries, Inc.</b>
Location	Farmingdale, NJ, US
Contact	LASLEY
510(k) history	4 submissions · 4 cleared · 1985-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853971/>, 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 27, 2026