

**K970165 EVITA 2 DURA**Aug 26, 1997  
222 days to decisionK970165 · Product code: **CBK** · AnesthesiologySource: <https://www.510kdatabase.net/k970165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jan 16, 1997
Decision date	Aug 26, 1997
Days to decision	222 days
Third-party review	No

**APPLICANT**

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Company	<b>Drager, Inc.</b>
Location	Pittsburgh, PA, US
Contact	HAROLD KNEUER
510(k) history	20 submissions · 15 cleared · 1991-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970165/>; 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 26, 2026