

**K253647 Evita (V800)**May 7, 2026  
168 days to decisionK253647 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k253647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Nov 20, 2025
Decision date	May 7, 2026
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Evita (V600)

**APPLICANT**

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Company	<b>Draegerwerk AG &amp; CO Kгаа</b>
Location	L?beck, DE
Contact	Holger Nadler
510(k) history	8 submissions · 8 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253647/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 19, 2026