

**K111640 PRECISION FLOW(R) - HELIOX**Oct 7, 2011  
116 days to decisionK111640 · Product code: **BTT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k111640/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Jun 13, 2011
Decision date	Oct 7, 2011
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vapotherm, Inc.</b>
Location	Annapolis, MD, US
Contact	GREGORY A WHITNEY
Website	<a href="https://vapotherm.com/">https://vapotherm.com/</a>
510(k) history	13 submissions · 12 cleared · 2000-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111640/> 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