

**K222822 VentStar Helix dual heated (N) Plus (MP02650),  
VentStar Helix heated (N) Plus (MP02608)**Jun 14, 2023  
268 days to decisionK222822 · Product code: **BZE** · Anesthesiology  
Source: <https://www.510kdatabase.net/k222822/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heater, Breathing System W/wo Controller (not Humidifier Or Nebulizer (BZE)
Date received	Sep 19, 2022
Decision date	Jun 14, 2023
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Draegerwerk AG &amp; CO Kga</b>
Location	L?beck, DE
Contact	Jan Upmeier
510(k) history	7 submissions · 7 cleared · 2010-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222822/> 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 May 26, 2026