

**K221836 Filter CareStar Plus, Filter SafeStar Plus, Filter/HME  
TwinStar Plus**Dec 7, 2022  
167 days to decisionK221836 · Product code: **CAH** · General Hospital  
Source: <https://www.510kdatabase.net/k221836/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Jun 23, 2022
Decision date	Dec 7, 2022
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Drägerwerk AG &amp; Co KGaA</b>
Location	Luebeck, DE
Contact	Luise Lang
510(k) history	4 submissions · 4 cleared · 2022-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221836/> 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 24, 2026