

**K231362 OCS Heart Leukocyte Depleting Filter**Oct 31, 2023  
173 days to decisionK231362 · Product code: **DTM** · CardiovascularSource: <https://www.510kdatabase.net/k231362/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	May 11, 2023
Decision date	Oct 31, 2023
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>TransMedics, Inc.</b>
Location	Andover, MA, US
Contact	Miriam Provost
510(k) history	3 submissions · 3 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231362/> 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