

**K083834 TERUMO PALL AL6X ARTERIAL FILTER**Apr 17, 2009  
115 days to decisionK083834 · Product code: **DTM** · CardiovascularSource: <https://www.510kdatabase.net/k083834/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Dec 23, 2008
Decision date	Apr 17, 2009
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Cardiovascular Systems Corp.</b>
Location	Elkton, MD, US
Contact	EILEEN DORSEY
510(k) history	43 submissions · 43 cleared · 2000-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083834/> 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