

**K163531 Advanced Perfusion System 1**Jun 7, 2017  
173 days to decisionK163531 · Product code: **DTQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k163531/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	Dec 16, 2016
Decision date	Jun 7, 2017
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Cardiovascular Systems Corporation</b>
Location	Elkton, MD, US
Contact	BRYAN HANN
510(k) history	29 submissions · 29 cleared · 2002-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163531/> 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 14, 2026