

**K140774 TERUMO CAPIOX FX15 AND FX25 HOLLOW FIBER  
OXYGENATOR/RESERVOIR**Jun 2, 2014  
66 days to decisionK140774 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k140774/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 28, 2014
Decision date	Jun 2, 2014
Days to decision	66 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	EILEEN DORSEY
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/k140774/> 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 June 6, 2026