

**K153213 Capiox RX Hollow Fiber Oxygenator with/without  
Hardshell Reservoir**Dec 3, 2015  
28 days to decisionK153213 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153213/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Nov 5, 2015
Decision date	Dec 3, 2015
Days to decision	28 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	Tierra A Brown
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/k153213/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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