

**K130280 CAPIOX FX HOLLOW FIBER OXYGENATOR W/  
RESERVOIR**Mar 13, 2013  
36 days to decisionK130280 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k130280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 5, 2013
Decision date	Mar 13, 2013
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Corporation</b>
Location	Shibuya-Ku, Tokyo, JP
Contact	GARRY A COURTNEY, MBA, RAC
510(k) history	13 submissions · 13 cleared · 2012-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130280/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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