

**K051997 CAPIOX RX15 HOLLOW, FIBER OXYGENATOR  
WITH/WITHOUT HARDSHELL RESERVOIR**Sep 15, 2005  
52 days to decisionK051997 · Product code: DTZ · Cardiovascular  
Source: <https://www.510kdatabase.net/k051997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 25, 2005
Decision date	Sep 15, 2005
Days to decision	52 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	GARRY A COURTNEY
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/k051997/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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