

**K010443 CAPIOX SX10 HOLLOW FIBER OXYGENATOR  
WITH/WITHOUT HARDSHELL RESERVOIR WITH X-COATING**

Dec 11, 2001  
300 days to decision

K010443 · Product code: DTZ · Cardiovascular  
Source: <https://www.510kdatabase.net/k010443/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 14, 2001
Decision date	Dec 11, 2001
Days to decision	300 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/k010443/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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