

**K003604 ADAPTERS WITH X-COATING**Feb 7, 2001  
78 days to decisionK003604 · Product code: **DTL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k003604/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Nov 21, 2000
Decision date	Feb 7, 2001
Days to decision	78 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/k003604/> 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 May 25, 2026