

**K013578 PUMP TUBING**Jan 22, 2002  
85 days to decisionK013578 · Product code: **DWE** · CardiovascularSource: <https://www.510kdatabase.net/k013578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Pump, Cardiopulmonary Bypass (DWE)
Date received	Oct 29, 2001
Decision date	Jan 22, 2002
Days to decision	85 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/k013578/> 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