

**K071521 TERUMO HX2 TEMPERATURE MANAGEMENT SYSTEM**Nov 21, 2007  
170 days to decisionK071521 · Product code: **DWC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k071521/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	Jun 4, 2007
Decision date	Nov 21, 2007
Days to decision	170 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	MARK A BUR
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/k071521/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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