

**K133658 CDI BLOOD PARAMETER MONITORING SYSTEM 500**Jul 25, 2014  
240 days to decisionK133658 · Product code: **DRY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k133658/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Nov 27, 2013
Decision date	Jul 25, 2014
Days to decision	240 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	Kevin Kong
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/k133658/> 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