

**K123984 QUANTIEN MEASUREMENT SYSTEM**Mar 28, 2013  
92 days to decisionK123984 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k123984/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 26, 2012
Decision date	Mar 28, 2013
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radi Medical Systems AB</b>
Location	Uppsala, SE
Contact	ANNA-LISA TIENSUU
510(k) history	24 submissions · 24 cleared · 1990-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123984/> 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 21, 2026