

**K134044 EP-TRACER SYSTEM, EP-TRACER SYSTEM, EP-TRACER SYSTEM**Mar 31, 2014  
90 days to decisionK134044 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k134044/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 31, 2013
Decision date	Mar 31, 2014
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardio Tek, BV</b>
Location	Ballwin, MO, US
Contact	MELISSA WALKER
510(k) history	2 submissions · 2 cleared · 2014-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k134044/> 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 June 2, 2026