

K161245 EP-TRACER SystemAug 5, 2016
94 days to decisionK161245 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k161245/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 3, 2016
Decision date	Aug 5, 2016
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardio Tek, BV
Location	Ballwin, MO, US
Contact	OLIVER ROTH
510(k) history	2 submissions · 2 cleared · 2014-2016

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