

K183266 EP-TRACER SystemMar 1, 2019
98 days to decisionK183266 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k183266/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Nov 23, 2018
Decision date	Mar 1, 2019
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Schwarzer Cardiotek GmbH
Location	Heilbronn, DE
Contact	Tatjana Nuber
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Graematter, Inc.
Contact	Melissa Walker

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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