

K223787 ECGenius SystemAug 4, 2023
228 days to decisionK223787 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k223787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 19, 2022
Decision date	Aug 4, 2023
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cath Vision Aps
Location	Copenhagen N, DK
Contact	Mads Matthiesen
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Graematter, Inc.
Contact	Sharon Bishop

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

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