

**K220306 ECGenius System**May 3, 2022  
90 days to decisionK220306 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k220306/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Feb 2, 2022
Decision date	May 3, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Graematter, Inc.</b>
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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