

K213861 CER-SApr 25, 2022
136 days to decisionK213861 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k213861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 10, 2021
Decision date	Apr 25, 2022
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiocalm Srl
Location	Montichiari, IT
Contact	Fabio Badilini
510(k) history	2 submissions · 2 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213861/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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