

K202094 Cardiovascular Suite 4.2.1Jan 11, 2022
532 days to decisionK202094 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k202094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jul 28, 2020
Decision date	Jan 11, 2022
Days to decision	532 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quipu S.R.L
Location	Pisa, IT
Contact	Vincenzo Gemignani
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Thomas Regulatory Resolutions, Inc.
Contact	Dallas L. Thomas

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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