

**K213972 Mac-Lab Recording Systems Altix, CardioLab
Recording Systems Altix, ComboLab Recording Systems Altix,
MLCL Client Software Altix**Feb 17, 2022
59 days to decisionK213972 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k213972/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 20, 2021
Decision date	Feb 17, 2022
Days to decision	59 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare Information Technologies, Inc.
Location	Wauwatosa, WI, US
Contact	James T Turner
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213972/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026