

K243540 Mac-Lab (AltiX AI.i)Dec 12, 2024
27 days to decisionK243540 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k243540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Nov 15, 2024
Decision date	Dec 12, 2024
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CardioLab (AltiX AI.i); ComboLab (AltiX AI.i); MLCL Client Software (AltiX AI.i)

APPLICANT

Company	Ge Medical Systems Information Technologies, Inc.
Location	Milwaukee, WI, US
Contact	James Turner
510(k) history	31 submissions · 31 cleared · 2010-2026

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