

**K231870 CASE V7.0 Cardiac Testing System and CardioSoft
V7.0 Cardiac Testing System**Dec 13, 2023
170 days to decisionK231870 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k231870/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jun 26, 2023
Decision date	Dec 13, 2023
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231870/> 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 13, 2026