FDA 510(k) Premarket Notification

CLEARED

K231870 CASE V7.0 Cardiac Testing System and CardioSoft V7.0 Cardiac Testing System

Dec 13, 2023
170 days to decision

K231870 · 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