

K202189 GraffitiDec 8, 2020
126 days to decisionK202189 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k202189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 4, 2020
Decision date	Dec 8, 2020
Days to decision	126 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	Camille Vidal
510(k) history	31 submissions · 31 cleared · 2010-2026

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