

K161465 CardioConfirmSep 3, 2016
99 days to decisionK161465 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k161465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 27, 2016
Decision date	Sep 3, 2016
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mortara Instrument, Inc.
Location	Walker, MI, US
Contact	Margaret Mucha
510(k) history	51 submissions · 51 cleared · 1983-2019

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