

K180432 AI-ECG PlatformNov 19, 2018
272 days to decisionK180432 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k180432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Feb 20, 2018
Decision date	Nov 19, 2018
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Carewell Electronics., Ltd.
Location	Shenzhen, CN
Contact	Chang Liu
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	FDA Regulatory and Quality Systems Consultant
Contact	Arthur Goddard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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