

**K200036 AI-ECG Tracker**Mar 20, 2020  
72 days to decisionK200036 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k200036/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jan 8, 2020
Decision date	Mar 20, 2020
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Carewell Electronics Co., Ltd.</b>
Location	Shanghai, CN
Contact	Chang Liu
510(k) history	2 submissions · 2 cleared · 2012-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>FDA Regulatory and Quality Systems Consultant</b>
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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