

K113485 ELECTROCARDIOGRAPHApr 25, 2012
154 days to decisionK113485 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k113485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Nov 23, 2011
Decision date	Apr 25, 2012
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Carewell Electronics Co., Ltd.
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	2 submissions · 2 cleared · 2012-2020

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