

K133985 DIGITAL ELECTROCARDIOGRAPHJan 22, 2015
392 days to decisionK133985 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k133985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 26, 2013
Decision date	Jan 22, 2015
Days to decision	392 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	5 submissions · 5 cleared · 2014-2016

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