

K123816 DIGITAL ELECTROCARDIOGRAPHSFeb 27, 2013
77 days to decisionK123816 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k123816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph (DPS)
Date received	Dec 12, 2012
Decision date	Feb 27, 2013
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Biocare Electronics Co., Ltd.
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	5 submissions · 5 cleared · 2010-2013

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