

K122712 DIGITAL ELECTROCARDIOGRAPHOct 25, 2012
51 days to decisionK122712 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k122712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph (DPS)
Date received	Sep 4, 2012
Decision date	Oct 25, 2012
Days to decision	51 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122712/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026