

**K101876 DIGITAL ELECTROCARDIOGRAPH, MODELS
ECG-1210, ECG-1230, ECG-3010, ECG-6010**Mar 1, 2011
238 days to decisionK101876 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k101876/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 6, 2010
Decision date	Mar 1, 2011
Days to decision	238 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/k101876/> 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