

**K163607 ECG Acquisition Systems**Dec 15, 2017  
359 days to decisionK163607 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k163607/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 21, 2016
Decision date	Dec 15, 2017
Days to decision	359 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vales &amp; Hills Biomedical Tech. , Ltd.</b>
Location	Shanghai, CN
Contact	Jianfang Liu
510(k) history	2 submissions · 2 cleared · 2013-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163607/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 31, 2026