

**K232816 Electrocardiograph, model: ECG301**Jun 7, 2024  
268 days to decisionK232816 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k232816/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Sep 13, 2023
Decision date	Jun 7, 2024
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen LE Medical Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Wuyaxiong .
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232816/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026