

**K172862 Portable ECG Monitor (ECG3)**Jul 24, 2018  
307 days to decisionK172862 · Product code: **DSH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k172862/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 20, 2017
Decision date	Jul 24, 2018
Days to decision	307 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Andon Health Co, Ltd.</b>
Location	Tiajin, CN
Contact	Liu Yi
510(k) history	92 submissions · 92 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172862/> 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 30, 2026