

**K252839 ZywieZ3 Sensor & Adhesive**Jun 18, 2026  
286 days to decisionK252839 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k252839/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Sep 5, 2025
Decision date	Jun 18, 2026
Days to decision	286 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zywie, Inc.</b>
Location	Johns Creek, GA, US
Contact	Latha Ganeshan
510(k) history	2 submissions · 2 cleared · 2015-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252839/> 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 July 11, 2026