

**K001634 CARDIOSENTRY EVENT MONITOR, MODEL 8470-01**Dec 21, 2000  
209 days to decisionK001634 · Product code: **DXH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k001634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	May 26, 2000
Decision date	Dec 21, 2000
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tz Medical, Inc.</b>
Location	West Linn, OR, US
Contact	BYRON ZAHLER
510(k) history	14 submissions · 14 cleared · 1992-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001634/> 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