

**K243566 CardioTag™**Jul 22, 2025  
246 days to decisionK243566 · Product code: **DXR** · CardiovascularSource: <https://www.510kdatabase.net/k243566/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ballistocardiograph (DXR)
Date received	Nov 18, 2024
Decision date	Jul 22, 2025
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiosense, Inc.</b>
Location	Chicago, IL, US
Contact	Arezou Azar
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243566/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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