FDA 510(k) Premarket Notification

K243566 CardioTag™

CLEARED

Jul 22, 2025
246 days to decision

K243566 · Product code: **DXR** · Cardiovascular
Source: https://www.510kdatabase.net/k243566/

SUBMISSION DETAILS

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

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