FDA 510(k) Premarket Notification

K243252 ZBPro Diagnostic

CLEARED

Jul 10, 2025
268 days to decision

K243252 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k243252/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Oct 15, 2024
Decision date	Jul 10, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zbeats, Inc.**
Location	Stony Brook, NY, US
Contact	Bin Fang
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Zaliance Medical Solutions**
Contact	Christopher Ford

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov