FDA 510(k) Premarket Notification

K252839 ZywieZ3 Sensor & Adhesive

CLEARED

Jun 18, 2026
286 days to decision

K252839 · Product code: **MWJ** · Cardiovascular
Source: https://www.510kdatabase.net/k252839/

SUBMISSION DETAILS

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

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