FDA 510(k) Premarket Notification

K250793 RhythmStar System (SL)

CLEARED

Apr 21, 2026
403 days to decision

K250793 · Product code: **QYX** · Cardiovascular
Source: https://www.510kdatabase.net/k250793/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Outpatient Cardiac Telemetry (QYX)
Date received	Mar 14, 2025
Decision date	Apr 21, 2026
Days to decision	403 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**RhythMedix, LLC**
Location	Minneapolis, MN, US
Contact	Stan Biletsky
510(k) history	3 submissions · 3 cleared · 2014-2026

REGULATORY CONSULTANT

Consulting firm	**MethodSense, Inc.**
Contact	Rita King

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