

K250793 RhythmStar System (SL)Apr 21, 2026
403 days to decisionK250793 · 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	RhythmMedix, 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

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