

K233584 RhythmStar SystemJul 8, 2024
244 days to decisionK233584 · Product code: **QYX** · Cardiovascular
Source: <https://www.510kdatabase.net/k233584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Outpatient Cardiac Telemetry (QYX)
Date received	Nov 7, 2023
Decision date	Jul 8, 2024
Days to decision	244 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233584/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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