FDA 510(k) Premarket Notification

K233584 RhythmStar System

CLEARED

Jul 8, 2024
244 days to decision

K233584 · 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