FDA 510(k) Premarket Notification

**CLEARED**

# K241179 Rhythm Express Remote Cardiac Monitoring System (RX-1 mini)

Jul 11, 2025
438 days to decision

K241179 · Product code: **QYX** · Cardiovascular
Source: https://www.510kdatabase.net/k241179/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Outpatient Cardiac Telemetry (QYX) |
| Date received | Apr 29, 2024 |
| Decision date | Jul 11, 2025 |
| Days to decision | 438 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Vivaquant, Inc.** |
| Location | St. Paul, MN, US |
| Contact | Brian Brockway |
| 510(k) history | 3 submissions · 3 cleared · 2019-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **DuVal & Associates, P.A.** |
| Contact | Kathy Herzog |

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